GYROLAB USER GUIDE

Original version

© Copyright 2015 Gyros, P0004354/H, D0023573/A

GYROS

Content

A Introduction

1 Important user information. A-3

2 Introduction to the Gyrolab platform A-5

3 Gyrolab immunoassay workflow. A-19

B Perform immunoassays on Gyrolab Instrument

1 Labelling of capture and detection reagents B-5

2 Gyrolab instrument startup procedure B-13

3 Design run B-17

4 Prepare samples and reagents. B-49

5 Start Run procedures B-55

6 After Run procedures and result export. B-67

C Data analysis

1 Introduction to data evaluation. C-5

2 Log in, main menu functions and analysis administration C-7

3 Manage analysis projects C-17

4 Analyze data C-29

5 Gyrolab Evaluator installation on office computer . C-45

D Gyrolab software add-on modules

1 Gyrolab Viewer D-5

2 Gyrolab ADA Software D-13

3 Gyrolab LIMS Interface D-37

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

4 Gyrolab Control Report D-47
5 Gyrolab Serial Dilution Analysis D-51

E Recipes

1 Recipes. E-3

F System administration and configuration

1 Gyrolab Control F-5
2 Gyrolab Administration Tool F-29
3 Gyrolab Result Database Explorer F-57
4 Gyrolab Database Backup Manager F-65
5 Gyrolab Set System Time F-67

G Troubleshooting

1 Instrument issues G-3
2 Software issues G-9
3 Application issues G-11

H Appendices

1 Products, accessories and consumables H-3
2 Custom Run workflow. H-7

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

GYROLAB USER GUIDE

A Introduction

Contents

A1 Important user information A-3

A1.1 User manuals A-3

A1.2 Intended use A-3

A1.3 Disclaimer A-3

A1.4 Symbols A-3

A1.5 User training A-4

A1.6 Trademarks A-4

A1.7 Patents A-4

A1.8 Designation A-4

A2 Introduction to the Gyrolab platform A-5

A2.1 Products included on purchase of a Gyrolab Instrument A-5

A2.1.1 GL Degasser (Gyrolab xP) A-5

A2.2 Gyrolab instrument front view A-6

A2.2.1 Gyrolab xP A-6

A2.2.2 Gyrolab xPlore A-8

A2.3 Gyrolab instrument rear view A-10

A2.3.1 Gyrolab xP A-10

A2.3.2 Gyrolab xPlore A-12

A2.4 Gyrolab CD microlaboratories A-13

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A2.4.1 Gyrolab Bioaffy CDs A-13
A2.4.2 Gyrolab Mixing CD A-14
A2.5 Rexxip buffers A-15
A2.6 Gyrolab software A-15
A2.6.1 Standard software A-15
A2.6.2 Additional software A-15
A2.6.3 Gyrolab software user levels A-16
A2.6.4 Gyrolab software terminology list A-16

A3 Gyrolab immunoassay workflow A-19

A3.1 Gyrolab workflow options A-19
A3.1.1 Wizard Run A-19
A3.1.2 LIMS Run A-19
A3.1.3 Custom Run A-20
A3.2 Gyrolab methods A-20
A3.3 Run setup and recommendations A-21
A3.3.1 Standard samples and Blanks A-21
A3.3.2 Calibration Controls A-21
A3.3.3 Unknown samples A-21
A3.3.4 Quality Controls A-21
A3.4 Assay optimization A-22
A3.4.1 Capture reagent concentration A-22
A3.4.2 Detection reagent concentration A-22
A3.4.3 Evaluation of PMT: Fluorescence detector settings A-23

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A1 Important user information

A1.1 User manuals

Gyrolab Instrument Guide is the main manual for the Gyrolab™ system. It contains basic operational instructions, maintenance procedures and safety information. It also holds guidance on how to decontaminate the instrument which is mandatory before a service visit if the system has been exposed to biohazards. Gyrolab Instrument Guide is found in the instrument binder. There are two versions of Gyrolab Instrument Guide one for Gyrolab xP and one for Gyrolab xPlore.

Gyrolab User Guide contains detailed information on system usage. This Gyrolab User Guide is valid for Gyrolab xP product no. P0004943, Gyrolab xPlore product no. P0020300 and Gyrolab Workstation product no. P0001661 with software Gyrolab Control 6.0 and Gyrolab Evaluator 3.3 or higher.

Gyrolab Quick Guide is a short instruction that describes the most common tasks performed with the Gyrolab system.

A1.2 Intended use

The Gyrolab Instrument is a flexible instrument platform used for running Gyrolab CD microlaboratories. The CDs are designed for development and processing of miniaturized immunoassays. Products are for research use only. Not for use in diagnostic procedures.

A1.3 Disclaimer

Do not use the Gyrolab instrument, or other products from Gyros in any way other than described in Gyrolab Instrument Guide or other documentation provided by Gyros. The built-in safety functions of the system may be reduced if operations not described in Gyrolab Instrument Guide are performed.

Gyros will use reasonable efforts to include accurate and up-to-date information in this document, but Gyros makes no warranties or representations of any kind as to its accuracy, currency or completeness. You agree that the use of this document and the content thereof is at your own risk. Gyros disclaims all warranties, expressed or implied, including warranties of satisfactory quality or fitness for a particular purpose. Neither Gyros nor any party involved in creating, producing or delivering this document shall be liable for any damages arising out of access to this document, or any errors or omissions in the content thereof.

A1.4 Symbols

The following symbols are used throughout Gyrolab User Guide to draw attention to important usage and safety issues when working with the Gyrolab instrument.

WARNING: Indicates a situation that could result in potential injury to operators of the equipment or those nearby. Situations highlighted with these precautionary symbols may also cause mechanical or electrical damage to the Gyrolab instrument.

CAUTION: Indicates an action or condition that could potentially damage equipment, data or materials. To disregard this caution may cause mechanical damage.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

NOTE: ***Provides and highlights information for the user that will help ensure proper execution of an action or procedure.***

TIP: ***Provides suggestions.***

A1.5 User training

Gyros provides Gyrolab user training. The system should not be used by personnel which has not been given this training.

A1.6 Trademarks

Gyros, Gyrolab, Gyrolab xPlore, Bioaffy, Rexxip and the Gyros logo are trademarks of Gyros Group. All other trademarks are the property of their respective owners.

A1.7 Patents

Products and technologies from Gyros are covered by one or more patents and/or proprietary intellectual property rights. All infringements are prohibited and will be prosecuted. Please contact Gyros AB for further details.

A1.8 Designation

The Product model name and commercial name for the Gyrolab xP system is Gyrolab xP. The Gyrolab xPlore system has the commercial name Gyrolab xPlore, and Product model name Gyrolab xPS.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A2 Introduction to the Gyrolab platform

A2.1 Products included on purchase of a Gyrolab Instrument

The Gyrolab Instrument is delivered with equipment and software needed for installation and usage of the system. Additional products can be ordered.

Purchase of a Gyrolab Instrument includes:

- Gyrolab instrument
- GL Degasser (only for Gyrolab xP)
- Wash solution bottles, pump liquid bottles and tubings
- Waste container
- Gyrolab User Guide, Gyrolab Instrument Guide and Gyrolab Quick Guide
- Start-up kit of Microplates, Microplate foil and Microplate foil adaptor
- Software: Gyrolab Control, Gyrolab Evaluator and administration software
- Four user licenses
- USB-stick, 1 GB

NOTE: ***A computer is required to control Gyrolab Instrument. The computer is purchased separately. See Gyrolab Instrument Guide for further information.***

A2.1.1 GL Degasser (Gyrolab xP)

NOTE: ***GL degasser is embedded in Gyrolab xPlore.***

GL Degasser is delivered with the Gyrolab system. Its intended use is to degas the buffers for the Syringe Pumps. For more information, refer to Instructions for GL Degasser.

The normal status for GL Degasser is:

- The green LED for Vacuum is lit.
- The yellow LED for Status is off.

NOTE: ***Always leave the GL Degasser on as long as the instrument is on.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A2.2 Gyrolab instrument front view

A2.2.1 Gyrolab xP

Figure 1: Gyrolab xP instrument front view

No	Part
1.	Microplate carousel where the microplates are loaded
2.	Microplate loading position
3.	Wash stations
4.	CD spinning unit with protective casing

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

No	Part
5.	CD vacuum arm
6.	CD loading position
7.	Liquid transfer device
8.	Syringe pumps (for the needles)
9.	Peristaltic pumps (for wash stations and waste)
10.	Hatch
11.	Connecting panel for external tubing
12.	Fluorescence detector
13.	Instrument buttons

- **MP** (Microplate) button
- **Fluorescence** button (present on some instruments)
- **CD** button

14. Instrument **Power** LED. Green light indicates that the instrument is on.
15. Instrument **Run** LED. Green light indicates that the instrument is performing a Run.
16. Instrument **Alarm** LED. Red light indicates that the instrument is in alarm state.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A2.2.2 Gyrolab xPlore

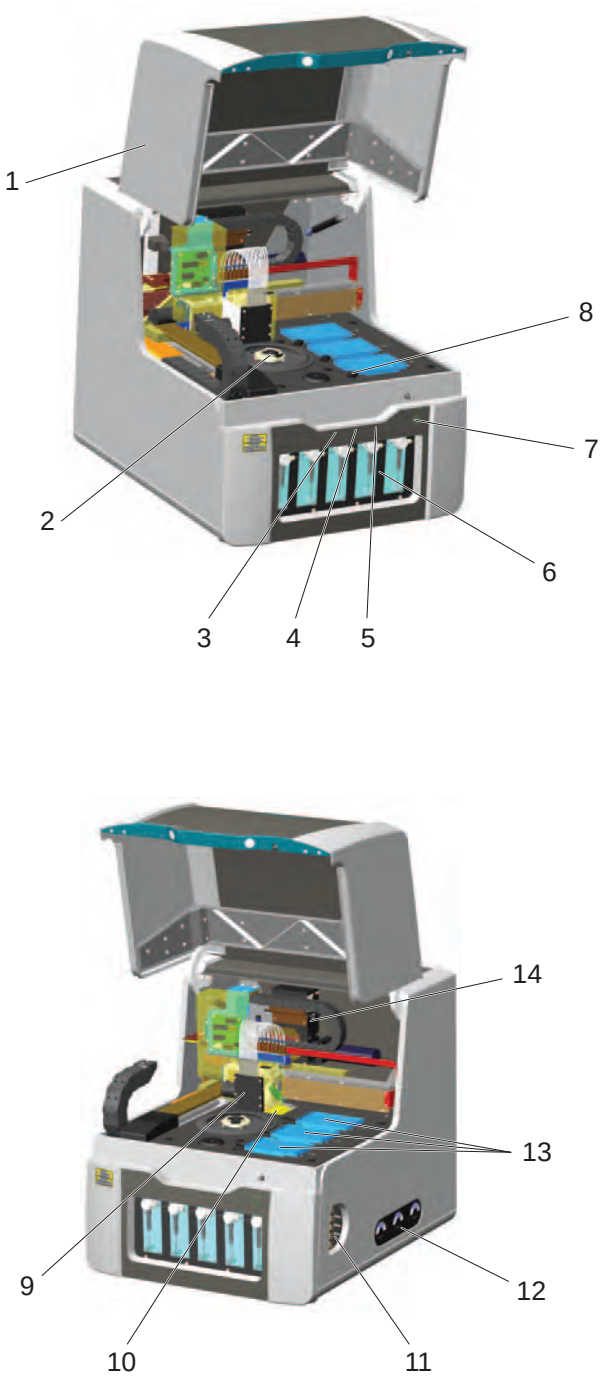


Figure 2: Gyrolab xPlore instrument front view

No	Part
1.	Hatch
2.	CD loading position and spinning unit with protective casing

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

No	Part
3.	Instrument **Ready** LED Green light indicates that the start-up sequence has finished and the instrument is ready for use.
4.	Instrument **Run** LED Green light indicates that the instrument is performing a Run.
5.	Instrument **Alarm** LED Red light indicates that the instrument is in alarm state.
6.	Syringe Pumps (for the needles)
7.	Power button
8.	Microplate locking lever
9.	Liquid transfer device
10.	Wash Stations
11.	Connecting panel for external tubing
12.	Peristaltic pumps (for Wash Stations and waste)
13.	Microplate positions (positions 1, 2 and 3)
14.	Fluorescence detector

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A2.3 Gyrolab instrument rear view

A2.3.1 Gyrolab xP

A2.3.1.1 Serial number less than GW10159

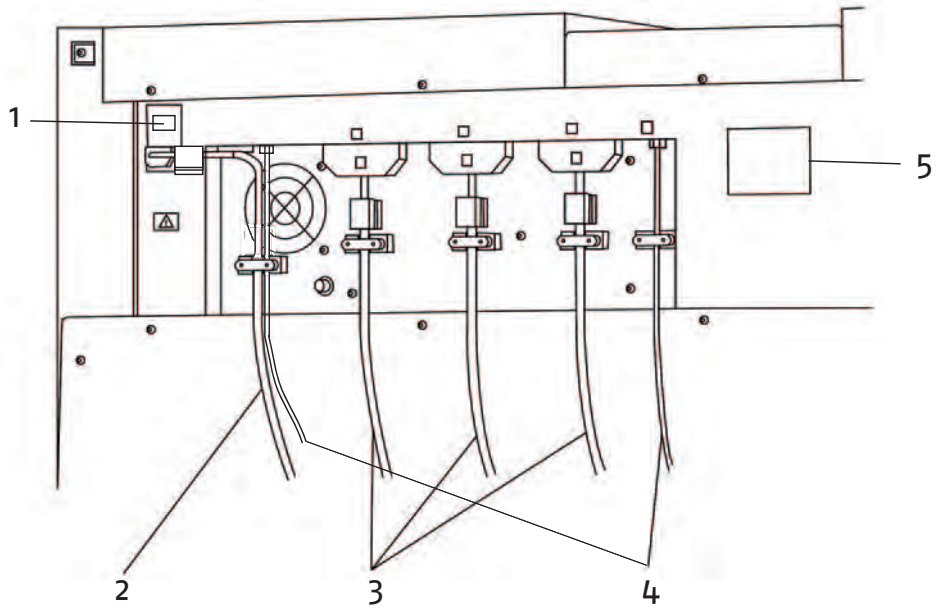


Figure 3: Gyrolab xP instrument rear view (serial number less than GW10159)

No	Part
1.	Power switch (0 = Off, I = On)
2.	Power cable
3.	Motor power cables
4.	USB connector
5.	Instrument label

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A2.3.1.2 Serial number GW10159 and higher

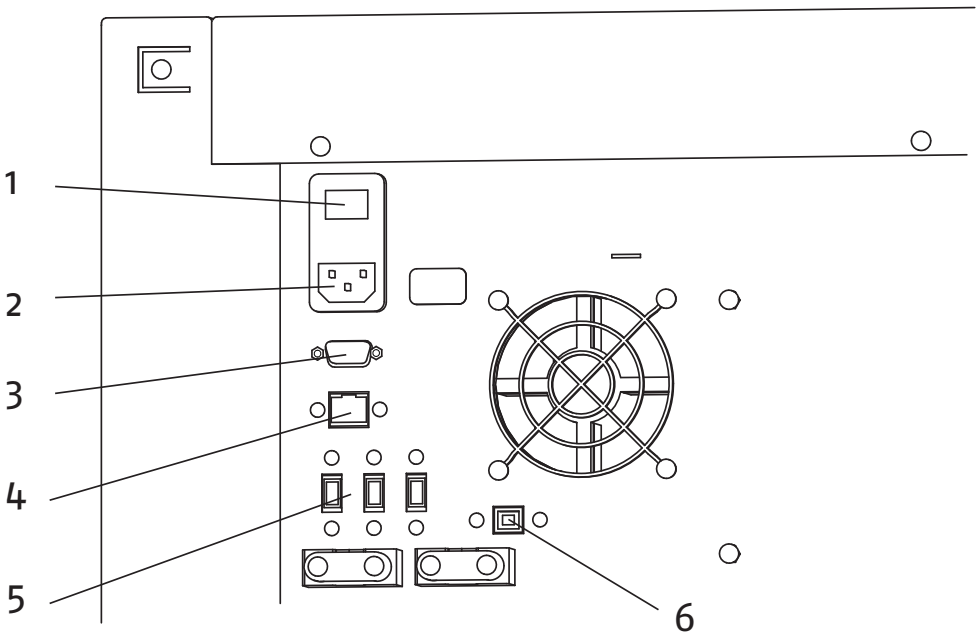


Figure 4: Gyrolab xP instrument rear view (serial number GW10159 and higher)

No	Part
1.	Power switch (0 = Off, I = On)
2.	Power cable connection
3.	VGA connection*
4.	Network connection* (RJ45)
5.	USB connectors* (3 pcs)
6.	USB for instrument control

* For service purposes only.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A2.3.2 Gyrolab xPlore

Figure 5: Gyrolab xPlore instrument rear view

No	Part
1.	Instrument label
2.	Mains power switch (0 = Off, I = On)
3.	Power cable connection
4.	USB for instrument control

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A2.4 Gyrolab CD microlaboratories

Gyrolab CD microlaboratories have been designed for efficient assay development and simple optimization for different analytes and different assay formats. All steps in a traditional immunoassay are automated, miniaturized and integrated into the CD. Within each CD, specific functional units in microstructures perform the individual assay steps required.

Microstructure columns are pre-packed with streptavidin-coated beads. The specificity of the microstructure is determined by addition of biotinylated reagents, allowing for total flexibility in assay design. For more detailed CD specifications and recommendations, refer to Product Information Sheets and Instructions For Use.

A2.4.1 Gyrolab Bioaffy CDs

Gyrolab Bioaffy CDs are intended for quantitative determination of analytes using miniaturized immunoassays. Bioaffy CDs contain a number of microstructures grouped into segments of 8 individual microstructures. Each microstructure has an individual sample inlet and a volume definition chamber that precisely defines the amount of sample and reagents applied to the column.

For each segment of microstructures there is a common sample inlet, enabling the same liquid to be added to all microstructures in that specific segment. See Figure 6 for a view of a Bioaffy CD microlaboratory and Figure 7 for details of an individual microstructure.

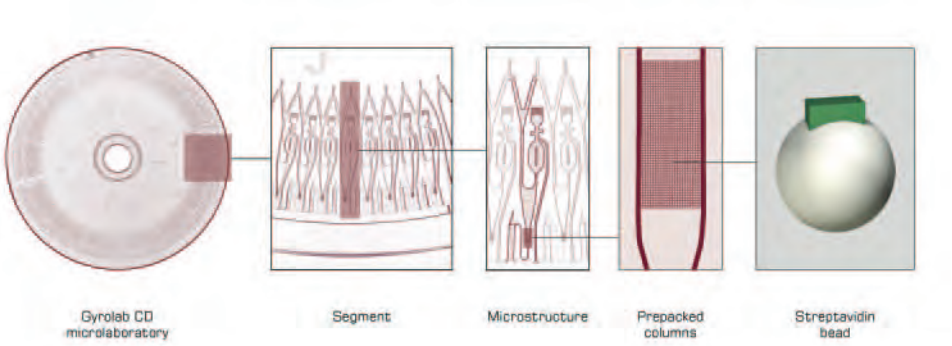


Figure 6: Gyrolab Bioaffy CD microlaboratory overview.

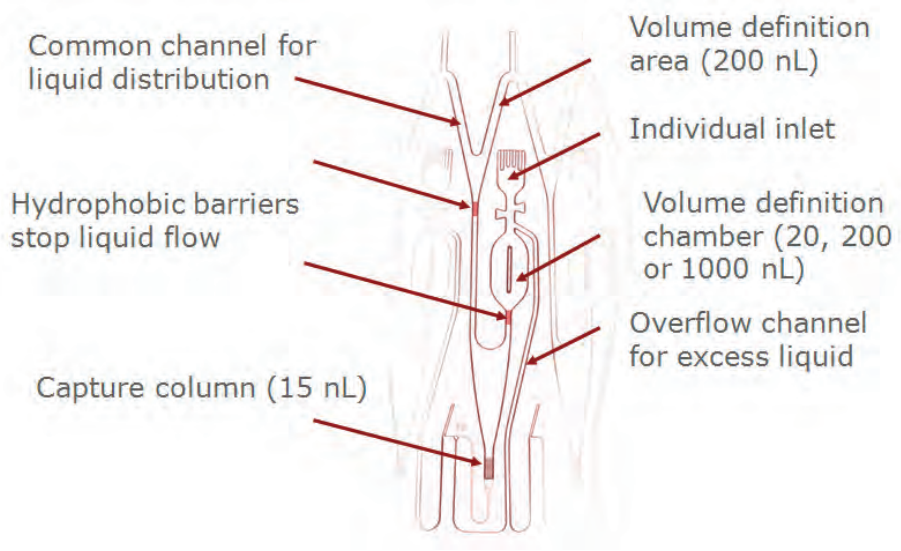

Common channel for liquid distribution
Volume definition area (200 nL)
Individual inlet
Hydrophobic barriers stop liquid flow
Volume definition chamber (20, 200 or 1000 nL)
Overflow channel for excess liquid
Capture column (15 nL)

Figure 7: Bioaffy CD microlaboratory microstructure showing functional units including the individual sample inlet.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

There are three different types of Bioaffy CDs available, Bioaffy 20 HC, Bioaffy 200 and Bioaffy 1000. The main difference between the three CDs is the sample volume applied over the column.

- **Gyrolab Bioaffy 20 HC** (8 microstructures × 14 segments => 112 microstructures) generates 20 nL sample volumes making it ideal for quantification in the mg/L range. This reduces the need for pre-analytical sample dilutions. Bioaffy 20 HC is suitable for quantification of drug product or contaminants, for example host cell proteins in crude cell supernatants.
- **Gyrolab Bioaffy 200** (8 microstructures × 14 segments => 112 microstructures) generates 200 nL sample volumes making it suitable for assays requiring a modest to low detection limit. This is useful for example for quantification of contaminating proteins requiring an assay working range at a modest analyte concentration.
- **Gyrolab Bioaffy 1000** (8 microstructures × 12 segments => 96 microstructures) generates 1000 nL sample volumes making it suitable for assays requiring a low detection limit. The detection limit is lowered compared to Bioaffy 200 in assays requiring an assay working range at very low analyte concentrations.

A2.4.2 Gyrolab Mixing CD

The detection of ADAs is a prime example of integrating sample pretreatment into the nanoliter-scale immunoassay workflow of Gyrolab Mixing CD. Addition of a mixing chamber allows for greater flexibility in assay workflows requiring additional incubations for equilibration, acid treatment or enzymatic reactions to occur. These additional assay steps typically add complexity and time to existing assays, while the Gyrolab Mixing CD not only integrates sample pretreatment, but also shortens assay and incubation times with its nanoliter-scale workflows. See Figure 8 for details of an individual Gyrolab Mixing CD microstructure.

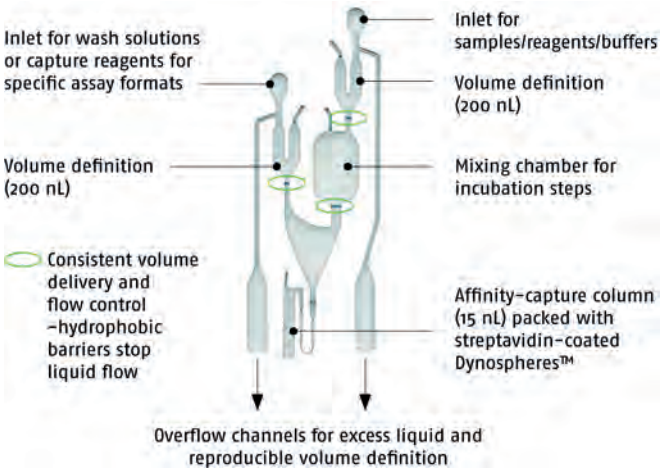

Inlet for wash solutions or capture reagents for specific assay formats
Volume definition (200 nL)
Consistent volume delivery and flow control -hydrophobic barriers stop liquid flow
Inlet for samples/reagents/buffers
Volume definition (200 nL)
Mixing chamber for incubation steps
Affinity-capture column (15 nL) packed with streptavidin-coated Dynospheres™
Overflow channels for excess liquid and reproducible volume definition

Figure 8: Gyrolab Mixing CD microlaboratory microstructure showing functional units.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A2.5 Rexxip buffers

Gyros provides Rexxip™ buffers for reagent and sample dilution. Rexxip buffers are optimized for all types of applications and CDs and for a variety of molecules with different analytical properties. Suitable Rexxip buffer should be selected considering sample type and species, analyte and assay format. Refer to Product Information Sheet for Rexxip buffers for recommendation on buffer selection.

A2.6 Gyrolab software

A2.6.1 Standard software

- Gyrolab Control: Gyrolab Control is the software used to control the Gyrolab instrument, set up experiments, process runs, and recover experimental data. Refer to Chapter F1 for details.
- Gyrolab Evaluator: Gyrolab Evaluator is used for evaluation of experiment raw data created by Gyrolab Control. Refer to Chapter C for details.
- Gyrolab Administration Tool: Gyrolab Administration Tool is used to manage administration and import/export of users, user access levels, CD microlaboratories, methods etc. For details. Refer to Chapter F2 for details.
- Gyrolab Result Database Explorer: Gyrolab Result Database Explorer is used for viewing results and report files, customize the database view, export results and report files and to generate status reports. refer to Chapter F3 for details.
- Gyrolab Database Backup Manager: Gyrolab Database Backup Manager is used for backing up of the database at a desired location either regularly or at specified time points. refer to Chapter F4 for details.
- Gyrolab Set System Time: Gyrolab Set System Time is used for changing system time. All changes of system time will be recorded in the audit trail. refer to Chapter F5 for details.
- Gyrolab Service Application: Gyrolab Service Application is intended only for Gyros service personnel.

A2.6.2 Additional software

A number software add-on modules are available:

- Gyrolab Viewer: The Gyrolab Viewer module for Gyrolab Control version 5.3 and Gyrolab Evaluator version 3.2 or higher converts on-column fluorescence data into a binding profile, revealing the interaction taking place on the column within each CD microstructure. The binding profiles are accessed through Gyrolab Evaluator. Gyrolab Viewer is used during assay development for relative ranking of binding affinity and to aid in the selection of optimal reagent pair. It is also used during quality control and assay troubleshooting to investigate outliers. Refer to Chapter D1 for details.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

- Gyrolab ADA Software: The Gyrolab ADA Software module for Gyrolab Control version 5.4 and Gyrolab Evaluator version 3.3 or higher is designed to analyze anti-drug antibodies (ADA) assays run on Gyrolab Mixing CD. During ADA analysis, clinical samples are screened for ADA positives in a screening assay. Confirmation assays are then performed to investigate whether positive samples from screening are true positives. Evaluation functionalities are available in Gyrolab ADA Software to support these analyses. Refer to Chapter D2 for details.
- Gyrolab LIMS Interface: The Gyrolab LIMS Interface module for Gyrolab Control version 5.2 or higher is compatible with the generic raw data file for Watson LIMS 6.4. The software module is designed to support users that carry out experiment set-up and data analysis within a LIMS system. Refer to Chapter D3 for details.
- Gyrolab Control Report: The Gyrolab Control Report module for Gyrolab Control version 5.2 or higher that enables automatic generation a condensed, printable, raw data report in pdf format after each run on the Gyrolab instrument. The generated report is compliant with 21 CFR Part 11 regulations and cannot be edited. The report includes raw data and general information about the run and experimental details. Refer to Chapter D4 for details.
- Gyrolab Serial Dilution Analysis: The Gyrolab Serial Dilution Analysis module for Gyrolab Evaluator version 3.2 or higher is used for automatic evaluation of spike recovery to verify the sample analysis accuracy using dilution series of spiked and unspiked unknown samples. Refer to Chapter D5 for details.

A2.6.3 Gyrolab software user levels

The users of Gyrolab software are given certain user levels, each user level given certain user rights (privilege) depending on their role in the laboratory flow and result generation. There are four user levels available: System Administrator, Project Manager, Method Developer and Operator. One additional user level is available for Gyros service personnel only, refer to Chapter F1.1.3 for details.

A2.6.4 Gyrolab software terminology list

Terminology used in the Gyrolab software and throughout this manual is explained in the list below.

Term	Description
Design Type	There are a number of workflows (or Design Types) available for setting up experiments and running assays on the Gyrolab system called Wizard Run, Custom Run and LIMS run (LIMS is an optional add-on module).
Loading List	A list generated during **Execute Run** procedures (Wizard Run) containing information of microplate location and volumes of samples and reagents.
Method	The method describes how the instrument handles samples, reagents and CDs.
Project	In Gyrolab Evaluator, a Project is a folder into which data from one or more Runs can be added. Within the Project Run data is analyzed and the analyzed data is saved and stored.
Reagent list	Used only for runs of design type Custom. The list holds information about samples and solutions in the transfer list, e.g. sample type and concentration.
Run	A Run is a collection of information required to perform a set of experiments on the instrument.
Sample List	The Sample List holds information about the samples in a run.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Term	Description
Sample	Sample is the common name for: • Unknown samples (samples to be analyzed) • Standard series (samples with known concentration used for standard curves) • Blanks (samples without protein added) • Calibration Controls (selected Standard samples used in CDs as controls in multi-CD runs.) • Quality Controls (spiked samples with known concentration used for quality evaluation but not used for standard curve)
Target	Targets define the output format and location for result files generated by the control software that are stored in the database and accessed by evaluation software.
Transfer list	Used only for runs of design type Custom. The list defines to which CD segments and structures samples and solutions are transferred and in what order.
Terminology used specifically in Gyrolab Evaluator:	
Structure folder	Structure folders are used to organize Projects in Gyrolab Evaluator, for example collect Projects within an experimental series or all assay development Projects in a specific Structure folder.
Project	Projects are entities in which analyses of one or more Runs is kept in Gyrolab Evaluator. Analysis setting may be locked for a Project. All analysis made in a Project are tracked in the Audit trail.
Run	Results from a Gyrolab Run. Results from Gyrolab Runs are selected by Run name for analysis in a Project.
Analyte	The Analyte subset of the Run results comprises all results using a certain assay for a certain substance. There can be one or more Analyte subsets in a Run.
Experiment	The Experiment subset of the Analyte results comprises all results using a certain combination of reagents at specific concentrations. There can be one or more Experiment subsets in a Analyte subset of a Run.
Data set	The Data set subset of the Experiment results comprises all results using a common standard curve. In some Runs a common standard curve is used for all CDs generating a single Data set subset per Experiment subset. In other Runs one standard curve per CD is used, generating a number of Data set subsets per Experiment subset.
PMT setting	Each Data set subset of samples is detected in Gyrolab using one or more PMT settings. Normally each sample is detected using three different PMT settings. In Quantification module analysis one or more PMT setting subsets are selected for inclusion in analysis reports.
Quantification analysis	Run results analyzed using Quantification module in Gyrolab Evaluator.
Data Comparison analysis	Results of comparison of Quantification Analyses using the Data Comparison module in Gyrolab Evaluator.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A3 Gyrolab immunoassay workflow

This section provides an introduction to immunoassay workflow, run recommendations and assay development on the Gyrolab platform. For further information and support on assay development, please contact Gyros.

A3.1 Gyrolab workflow options

There are three different workflow options, called Design types, available for performing immunoassays:

- Wizard
- LIMS (available as a software add-on module)
- Custom

The Design types differ mainly in the way that runs are set up and what output is generated.

A3.1.1 Wizard Run

The **Wizard Run** workflow is designed for a flexible but also easy entering of various experimental parameters. One or more analytes and sets of reagents can be used.

Gyrolab Control generates a Loading list with volume requirements for all types of samples, assay reagents and wash buffer. Alternatively, the Loading list can be created in LIMS. The loading list is used when preparing microplates.

A Sample List is automatically generated by the software or it can be created in Microsoft Excel. All Unknown samples are quantified against all combination of reagents.

Refer to Chapter B for more detailed information on Wizard workflow.

Recommended for:

- Assay development and assay optimization
- Routine analysis
- Validation experiments

A3.1.2 LIMS Run

The **LIMS Run** workflow allows integration of Gyrolab quantification analyses with LIMS. Contact Gyros for compatibility questions.

The **LIMS Run** workflow is designed for immunoassay work in combination with a LIMS. The **LIMS Run** workflow ensures traceability and efficient communication with LIMS by import of LIMS worklists and generation of output files for LIMS. The **LIMS Run** workflow is GxP compliant.

One assay and one set of reagents is used per Run. The **LIMS Run** workflow is not designed for assay optimization studies. Assay optimization is performed using the Wizard Run workflow.

Gyrolab Control generates a Loading list with volume requirements for all types of samples, assay reagents and wash buffer. Alternatively, the Loading list can be created in LIMS. The loading list is used when preparing microplates.

Refer to Chapter Chapter D3 for more detailed information on LIMS workflow.

NOTE: To use the LIMS Run workflow a license from Gyros is required to activate the add-on. A temporary license can be provided for a limited trial period. Please contact Gyros.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Recommended for:

- Routine analysis for users with a LIMS

A3.1.3 Custom Run

The **Custom Run** workflow is designed for maximal flexibility.

The **Custom Run** workflow allows the user to customize what samples are quantified towards what reagent set. Custom Run can be used when non-standard transfer from microplates to CD microlaboratories is required or when a variation of replicates for different samples and standard points for example during assay development is required.

No Loading List is generated. Transfer and Reagent List necessary.

Refer to Chapter Chapter H2 for more detailed information on Custom workflow.

Recommended for:

- Assay development and assay optimization experiments with special demands

A3.2 Gyrolab methods

Gyrolab methods are comparable to assay protocols. The assay run is automated within the Gyrolab workflow but is still as flexible as manual assay protocols.

Gyrolab methods are designed for one specific CD-type and Run Design Type. The method name describes what it is used for.

For example: **1000-3W-001-A**

- **1000** is the code for which CD type is used in the method
  - 20 = Gyrolab Bioaffy 20HC
  - 200 = Gyrolab Bioaffy 200
  - 1000 = Gyrolab Bioaffy 1000
  - ADA = Gyrolab Mixing CD
- **3** defines the number of steps the method has.
  - 3 = The standard method (3-step method): In this method 3 liquid transfers occur sequentially (washes not included). There is one capture addition, one analyte addition and one detection addition.
  - 1 = The 1-step method: In this method only one analyte addition occurs. This can for example be applicable when running a homogeneous assay where capture, analyte and detection reagent have been pre-mixed in a microplate prior to the run.
  - 2 = The 2-step method: This method contains one capture addition and one analyte addition.
  - 4 = The 4-step method: This method contains two capture additions, one analyte addition and one detection addition.
- **W** defines design type
  - W = wizard design type
  - C = custom design type
- **001** is a unique identity number for a specific combination on CD type, number of steps in the method and design type
- **A** stands for approved and official method released by Gyros and B for beta method released by Gyros

Methods can be customized by Gyros to suit specific needs. Contact Gyros for more information.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A3.3 Run setup and recommendations

A Run is a collection of information required to perform a set of experiments using the Gyrolab platform. The run is designed in and executed by Gyrolab Control software.

After each Run, results and statistics are analyzed with Gyrolab Evaluator software. Resulting column profiles can be examined using Gyrolab Viewer to facilitate assay optimization and evaluation of possible outliers.

The concentration of analyte in each unknown sample is quantified against a standard curve. It is also possible to include quality control samples in a run. Refer to Chapter A3.3.1 – Chapter for recommendations on how to set up a run that contribute to good data quality and facilitates data analysis.

A3.3.1 Standard samples and Blanks

In general, using Standard samples with many different concentrations in a Standard series facilitates generation of a high quality standard curve. However, this requires a larger number of microstructures on the CDs, leaving fewer microstructures available for analysis of unknown samples.

Set the highest and lowest concentration in a Standard series to be higher and lower, respectively, than the expected concentration range of the Unknown samples. This ensures the standard curve to be in a range where unknown concentrations can be determined. Use serial dilution steps of five or lower.

In addition to the Standard concentrations at least one blank sample must be included. Include at least duplicates of all unknown samples in the Run.

A3.3.2 Calibration Controls

The purpose of Calibration Control samples is to save CD structures for analysis of unknown samples in multi-CD runs. For each experiment, a standard series must be present on at least one CD. With the use of Calibration Controls on the remaining CDs instead of an entire Standard series structures are saved. It is recommended to use at least two Calibration Controls with concentrations corresponding to two different Standard sample concentrations.

When analyzing results, check that Calibration Control data do not differ from Standard series data for corresponding concentration values. If there is a significant difference discard the sample results from that particular CD. It is very important that the Standard sample and Calibration Control of the same concentration are from the identical aliquot.

A3.3.3 Unknown samples

Unknown samples are placed in designated sample microplates and information about each Unknown sample is entered into a Sample List to allow traceability of the generated results. Include at least duplicates of all unknown samples in the Run.

A3.3.4 Quality Controls

Quality Controls are samples that have been spiked with known analyte concentrations into identical sample matrix as present in your unknown samples. Quality Controls are used to ensure that the assay is working properly within a CD run and between runs over extended periods of time. A set of Quality Controls should be acquitted and stored under the same conditions as your unknown samples. Selected Quality Controls should be prepared independently from each other and from Standard series samples.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A3.4 Assay optimization

To ensure the best possible data quality each assay must be optimized.

A3.4.1 Capture reagent concentration

A concentration of 700 nM biotinylated capture reagent is sufficient to saturate the column. For each new batch of capture reagent, perform a test run analyzing samples with known concentration. Study resulting column profiles using Gyrolab Viewer, refer to Chapter D1, to ensure that the target protein is sufficiently enriched at the top of the column.

A3.4.2 Detection reagent concentration

The degree of detection reagent fluorophor labeling may affect immunoassay performance. When developing a new assay, perform a titration to determine the optimal detection reagent for the specific assay. When labelling a fresh batch of detection reagent for an assay that has already been optimized, a titration is not needed provided that the fluorophor to protein ratio is within recommended values (Chapter B1.2).

A lower detection reagent concentration gives lower background noise which allows for increased assay sensitivity. If the desired measurement is higher then the concentration of the detection reagent concentration must also be higher to still be in sufficient excess at the high concentration end of the measuring range. Always optimize detection reagent concentration towards expected sample concentration.

The data in Figure 1 displays results from a titration run in which detection reagent concentration was varied whilst capture reagent concentration was held fixed. For this assay a detection reagent concentration of 10 nM is recommended since this option gives the lowest limit of detection while still sufficiently concentrated to allow measurements in high end of the calibration curve.

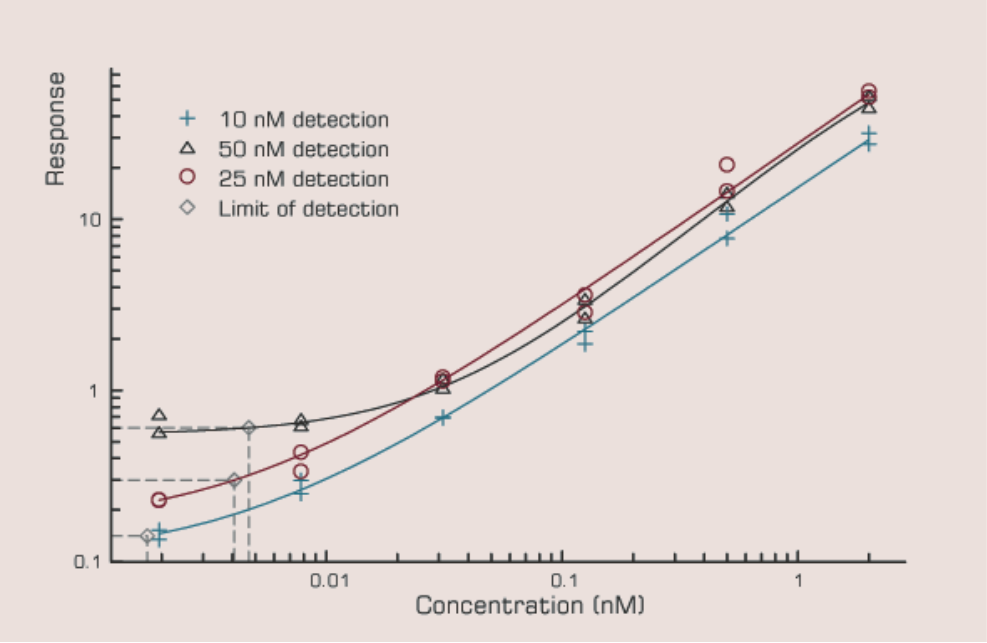


Figure 1: Standard curves for human IL-8 sandwich assay. The concentration of the detection antibody was varied to determine the optimal working concentration. Diamonds mark the limit of detection for the different concentrations.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

A3.4.3 Evaluation of PMT: Fluorescence detector settings

The fluorescent signal from the microstructure column is amplified by a photo multiplier tube (PMT) when the signal reaches the detector. The degree of amplification needed to obtain a sufficient response value depends on the signal intensity of the measured sample. The signal amplification is controlled by the PMT setting in a Gyrolab method. If the degree of amplification is too high, the detector will be saturated. If the PMT setting is too low weak signals may be lost in the background scatter.

To investigate proper amplification level (expressed in percentage of incoming signal amplification, % PMT), different PMT-levels can be tested in the same run. Normally three PMT-levels are included in the methods used during assay development phase to illustrate assay performance. When the assay is fully optimized it is sufficient to use one selected PMT setting. Refer to Chapter D1 for guidance on how to optimize PMT setting using the Gyrolab Viewer software module.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

GYROLAB USER GUIDE

B Perform immunoassays on Gyrolab Instrument

Contents

B1 Labelling of capture and detection reagents B-5

B1.1 Biotinylation of capture reagent B-5

B1.2 Fluorophore labeling of detection reagent B-7

B1.3 Buffer exchange, azide removal and protein concentration protocols B-9

B1.3.1 Nanosep 30K Protocol B-9

B1.3.2 Thermo Scientific spin column protocol B-10

B1.3.3 Concentrate reagent solution B-11

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B2 Gyrolab instrument startup procedure B-13

B2.1 Turn on instrument and GL Degasser B-13

B2.2 Start Gyrolab Control software B-13

B2.3 Initialize the system B-15

B2.4 Prime instrument B-16

B3 Design run B-17

B3.1 Instructions for Gyrolab xP

B3.1.1 Wizard run design introduction B-17

B3.1.2 Create or edit a Wizard Run B-18

B3.1.3 Sample List completion B-25

B3.1.4 Prepare Wizard Run B-28

B3.1.5 Macros for creating names for folders and files..... B-31

B3.2 Instructions for Gyrolab xPlore B-32

B3.2.1 Wizard run design introduction.....B-32

B3.2.2 Create or edit a Wizard Run B-32

B3.2.3 Sample List completion B-41

B3.2.4 Prepare Wizard Run B-44

B3.2.5 Macros for creating names for folders and files.....B-47

B4 Prepare samples and reagents B-49

B4.1 Instructions for Gyrolab xP B-49

B4.1.1 Reagents and samples B-49

B4.2.2 Load microplates B-53

B4.2 Instructions for Gyrolab xPlore B-52

B4.2.1 Reagents and samples B-52

B4.2.2 Load microplates B-53

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B5 Start Run procedures B-55

B5.1 Instructions for Gyrolab xP B-55

B5.1.1 Load Gyrolab instrument B-55

B5.1.2 Load CDs B-56

B5.1.3 Start Run B-60

B5.2 Instructions for Gyrolab xPlore B-61

B5.2.1 Load Gyrolab instrument B-61

B5.2.2 Load CDs B-65

B5.2.3 Start Run B-66

B6 After Run procedures and result export B-67

B6.1 Instructions for Gyrolab xP B-67

B6.1.1 Finish Run B-67

B6.1.2 How to turn Gyrolab off B-69

B6.1.3 Generated Gyrolab Control files B-70

B6.2 Instructions for Gyrolab xPlore B-71

B6.2.1 Finish Run B-71

B6.2.2 How to turn Gyrolab off B-72

B6.2.3 Generated Gyrolab Control files B-73

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B1 Labelling of capture and detection reagents

This chapter contains protocols for

- Biotinylation of capture reagent, Chapter B1.1
- Fluorophore labeling of detection reagent, Chapter B1.2
- Buffer exchange/protein concentration, Chapter B1.3

For recipes, refer to Chapter E1.

B1.1 Biotinylation of capture reagent

The following solutions and consumables are required:

- Biotinylation reagent
- Capture reagent
- Milli-Q® water
- PBS
- Protein Desalting Spin Column (Thermo Scientific), cutoff: 7K. For larger proteins consider using Nanosep 30K (Pall Life Sciences).
- 1.5–2.0 ml microcentrifuge collection tube

Step	Action
1.	**Preparation of capture reagent** Refer to supplier-provided instructions for the biotinylation reagent. The protocol in this chapter is based on instructions for EZ-Link Sulpho NHS-LC-Biotin (Thermo Scientific). Use 100 µl of 1 mg/ml capture reagent (antibody or other suitable capture reagent) for biotinylation labeling. The capture reagent to be biotinylated must be in a buffer free from stabilizing proteins (for example BSA), ammonium ions, primary amines, and sodium azide to obtain the best possible degree of labeling. • If the concentration of sodium azide in capture reagent solution is >3 mM (0.02%), remove the sodium azide, refer to Chapter B1.3. • If the capture reagent solution is in an amine-containing buffer, exchange buffer to PBS (pH 7.2 – 8.0), refer to Chapter B1.3. • If concentration of capture reagent solution is <1 mg/ml, concentrate capture reagent solution, refer to Chapter B1.3. • If concentration of capture reagent solution is >1 mg/ml, dilute with PBS. • If the capture reagent t is a powder lyophilized from an appropriate buffer, it is reconstituted in PBS.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

2. **Preparation of Biotinylation reagent**

- Allow biotinylation reagent (EZ-Link Sulfo-NHS-LC-Biotin) to reach room temperature.
- Dissolve 0.5–1 mg of the biotinylation reagent in ice-cold deionized/distilled water (Milli-Q water) to a final concentration of 1 mg/ml.
- Vortex gently.

3. **Biotin labeling procedure**

- Mix appropriate volumes of biotinylation reagent and capture reagent solution at a 12 times molar excess of biotinylation reagent compared to capture reagent.

TIP: **Formula:**
µmol capture reagent = µg capture reagent / (g/mol) capture reagent
µmol Biotin = 12 × µmol capture reagent
µg Biotin = µmol Biotin × (g/mol) Biotin (MW Biotin = 556 g/mol)

Example:
For 100 µg of 1 mg/ml IgG (MW 150 000 g/mol), add 4.5 µg Biotin reagent
µmol IgG = 100 µg / 150 000 g/mol = 0.000667 µmol IgG
µmol Biotin = 12 × 0.000667 µmol IgG = 0.008 µmol Biotin
µg Biotin = 0.008 µmol Biotin × 556 g/mol Biotin = 4.5 µg Biotin
(4.5 µg Biotin is 4.5 µl of a 1 mg/ml Biotin reagent solution)

- Vortex gently for a few seconds.
- Incubate 1 hour at room temperature while occasionally shaking the vial gently.

4. **Removal of unbound biotinylated reagent**

- Invert the Protein Desalting Spin Column (Thermo Scientific) to suspend slurry.
- Place the column in a collection tube and centrifuge at 1500 × g for one minute to remove excess liquid.
- Add the biotinylation mixture to the column center of the compacted resin bed. Be careful not to disturb the resin or to allow sample to flow around the resin bed.
- Centrifuge at 1500 × g for two minutes. Biotinylation mixture will be collected in the tube.
- Put the tube with biotinylation mixture on ice.
- Discard the column only after a proper separation of compounds in the biotinylation mixture is confirmed.

NOTE: ***This protocol step is only valid for proteins larger than 7kD. For smaller proteins use another method for removal of free biotin, for example Nanosep (Pall Life Sciences) with a suitable cutoff.***

5. **Concentration measurement of biotinylated reagent**

- Measure absorbance (A_{280}) of the biotinylated reagent. Dilute an aliquot of the biotinylated reagent 1:10 in PBS for absorbance measurement.
- Calculate reagent concentration (mg/ml):

  Reagent concentration (mg/ml) = (A_{280} × dilution factor) / ε × L

  ε = 1,38 (cm^{-1} $(mg/ml)^{-1}$), L = cuvette length in cm (1 cm)

NOTE: ***The extinction coefficient, ε, for IgG is 1,38 (cm^{-1} $(mg/ml)^{-1}$), other values may be valid for other reagents.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
6.	**Storage of biotinylated reagent** Aliquot and store the biotinylated capture reagent at +4 °C or -20 °C (long-term storage).
7.	**Verify biotinylation** Perform a Run using 700 nM of the biotinylated molecule (for an antibody this corresponds to 0.1 mg/ml). Evaluate results to verify a successful biotinylation.

TIP: Recalculations of concentration from g/L to molar terms
Formula: M protein = g/L protein / MW (g/mol) = mol/L protein
Example: For 1 mg/mL of BSA (MW 67000 g/mol): M BSA = 1 g/L / 67000 g/mol = 0.0000149 M = 14900 nM

TIP: The concentration of biotinylated capture reagent should be high enough to saturate the streptavidin column. Normally concentrations of around 700 nM of biotinylated protein is enough to saturate the column.

B1.2 Fluorophore labeling of detection reagent

The following solutions and consumables are required

Desired Fluorophore labeling kit

- Alexa Fluor 647 Monoclonal Antibody Labeling Kit (100 µg), proteins >30 kDa
- Alexa Fluor 647 Microscale Protein Labeling Kit (20-100 µg), proteins 20-150 kDa
- DyLight 649 Microscale Antibody Labeling Kit (100 µg), 50-150 kDa
- Detection reagent

Required solutions and consumables depend on which fluorophore labeling kit is used. Please refer to supplier-provided instructions for the fluorophore labeling kit.

Step	Action
1.	**Preparation of detection reagent** Refer to instructions for the fluorophore labeling kit for details. The protocol in this chapter follows instructions given in Alexa Fluor™ 647 Monoclonal Antibody Labeling Kit (Molecular Probes) for antibodies and proteins > 30 kDa. Use 100 µl of 1 mg/ml detection reagent (antibody or other suitable detecting reagent) for fluorophore labeling. The reagent to be fluorophore labeled must be in a buffer free of stabilizing proteins (for example BSA), ammonium ions, primary amines, and sodium azide to obtain the best possible degree of labeling. • If the concentration of sodium azide in detection reagent solution is >3 mM (0.02%), remove the sodium azide, refer to Chapter B1.3. • If the detection reagent solution is in amine-containing buffer, exchange buffer to 0.1 M Sodium bicarbonate buffer (pH 7.2 - 8.0), refer to Chapter B1.3. • If concentration of detection reagent is <1 mg/ml, concentrate detection reagent solution, refer to Chapter B1.3. • If concentration of detection reagent is >1 mg/ml, dilute with 0.1 M Sodium bicarbonate buffer. • If the reagent to be labeled is a powder lyophilized from an appropriate buffer, it is reconstituted in 0.1 M Sodium bicarbonate buffer.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

2. Fluorophore labeling procedure

- Add 1:10 volume of 1 M Sodium bicarbonate buffer to the 1 mg/ml detection reagent solution.

NOTE: This is not required if the starting material is lyophilized and already reconstituted in 0.1 M sodium bicarbonate buffer.

- Transfer 100 µl of detection reagent solution to vial containing Component A (reactive dye). Vortex gently to dissolve the reactive dye.
- Protect vial from light by wrapping it with aluminum foil.
- Incubate 1 hour at room temperature while shaking the vial gently.

3. Preparation of purification column

- Moisten purification column filter with 1 ml PBS. Pressured air may be required to elute the PBS.
- Stir purification resin (Component C) and add 1 ml to the column, allow it to settle.

NOTE: The purification resin is a 30.000 Mw size-exclusion resin. Do not use for proteins <30 kDa.

- Add additional purification resin until the bed volume is approximately 1.5 ml.
- Allow the column buffer to drain from the column by gravity.
- Place column in provided collection tube. Centrifuge at 1100 × g for 3 minutes.

4. Purification of fluorophore labeled detection reagent

- Load 100 µl of the labeled reagent onto the purification column.
- Place column in an empty collection tube.
- Centrifuge 1100 × g for 5 minutes.
- Transfer the labeled reagent in the collection tube to a dark vial.

5. Determination of concentration and labeling efficiency

- Measure absorbance of the purified fluorophore labeled detection reagent at A_{280} and A_{650}. Dilute an aliquot of the fluorophore reagent 1:10 in PBS for absorbance measurement.
- Calculate detection reagent concentration:
  Concentration (M) = $(A_{280} - (A_{650} \times 0.03)) \times$ dilution factor / ε,
  $\varepsilon = 203000$ (cm^{-1} M^{-1})

NOTE: The extinction coefficient, ε, for IgG at A_{280} = 203000 (cm^{-1} M^{-1}), other values may be valid for other reagents.

- Calculate degree of labeling (moles fluorophore per mole of detection reagent):
  Labeling degree = (A_{650} × dilution factor) / ε × Concentration (M))
  $\varepsilon = 239000$ (cm^{-1} M^{-1}) of fluorophore at A_{650}

NOTE: For antibodies a degree of labeling of 3-7 moles of fluorophore dye per mole of antibody is recommended.

6. Dilution and storage of fluorophore labeled detection reagent

- Dilute the fluorophore labeled reagents to 1000 nM in PBS, 0.2% BSA (Calbiochem).
- Aliquot and store fluorophore labelled detection reagent at -20 °C protected from light.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
7.	**Verify fluorophore labeling** • For all new assays, assay formats and newly labelled reagents, perform a titration Run to find the optimal concentration for the detection reagent, refer to Chapter A3.4.2. • For an established assay, perform a test Run using previously established concentration. Compare the result from the new batch of labelled reagent with results from previous batches in previous titration Runs.

B1.3 Buffer exchange, azide removal and protein concentration protocols

This chapter contains protocols for buffer exchange and reagent concentration.

B1.3.1 Nanosep 30K Protocol

The Nanosep 30K protocol (Pall Life Sciences), is used for buffer exchange and azide removal. Nanosep columns come in different cut off values (3, 10, 30 and 100K). The optimal filter size of the spin column depends on the size of the reagent.

The following solutions and consumables are required

- Nanosep 30K membrane (Pall Life Sciences) and sample reservoir
- Deionized water
- 1×PBS without NaN_3

Step	Action
1.	• Pre-rinse the Nanosep by filtering 500 µl deionized water or buffer through the membrane twice. • Spin up to 11 000 × g for a couple of minutes. Do not allow the membrane to dry out prior to use.
2.	• Pipette the required volume of protein (50 to 500 µl) into the sample reservoir. • Fill up to 400 µl with buffer. • Cap the Nanosep device. • Spin up to 11 000 × g for 2 – 20 minutes.
3.	• Wash 2–3 times with 200 – 400 µl buffer. • Spin up to 11 000 × g for 2 – 20 minutes.
4.	If the reagent appears to have spun dry in the device, the reagent is easily recovered by pipetting several times with approximately 50 µl buffer.
5.	Dilute the reagent with buffer to get a concentration of 1 mg/ml.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B1.3.2 Thermo Scientific spin column protocol

The protocol is copied from Thermo Scientific Protein Desalting Spin Columns, product number: 89849, which is designed for use on proteins with a M_W > 7000 Da.

Follow this protocol when using Desalting spin column for buffer exchange and azide removal.

The following solutions and material are required

- Thermo Scientific Protein Desalting Spin Column
- Variable-speed bench-top microcentrifuge
- 1.5–2 ml microcentrifuge collection tubes
- Equilibration buffer: PBS

A Protein Desalting Spin Columns Preparation

Step	Action
1.	Prepare the protein desalting spin column • Invert column to suspend slurry. • Twist off bottom closure and loosed cap. • Place column in 1.5–2 ml microcentrifuge collection tube. • Centrifuge at 1500 × g for 1 minute to remove excess liquid.
2.	Perform four column washes • Add 400 µl of equilibration buffer to the top of column. • Centrifuge the column at 1500 × g for 1 minute to remove excess liquid. • Discard buffer from the collection tube.

Sample Loading

Step	Action
1.	• Place column in a fresh collection tube and remove the cap. • Apply 30–120 µl of sample (proteins with M_W greater than 7000) to the center of the compacted resin bed. Be careful not to disturb the resin or to allow sample to flow around the resin bed.
2.	**Optional:** To improve recovery percentage of low molecular weight proteins or for small sample volumes, add 20–40 µl of equilibration buffer to top of resin. Do not exceed a total of volume of 120 µl.
3.	Centrifuge column at 1500 × g for 2 minutes. The desalted sample is collected in the collection tube.
4.	Discard the desalting column after use.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B1.3.3 Concentrate reagent solution

This protocol for reagent concentration uses Nanosep 30K (Pall Life Sciences). Nanosep columns come in different cut off values (3, 10, 30 and 100K). The optimal filter size of the spin column depends on the size of the reagent.

The following solutions and consumables are required

- Nanosep 30K membrane (Pall Life Sciences) and sample reservoir
- Deionized water
- 1×PBS without NaN_3.
- Thermo Scientific spin column protocol

Step	Action
1.	• Pre-rinse the Nanosep by filtering 500 µl deionized water or buffer through the membrane twice. • Spin up to 11 000 × g for a couple of minutes. Do not allow the membrane to dry out prior to use.
2.	• Pipette the required volume of protein (50 to 500 µl) into the sample reservoir. • Cap the Nanosep device. • Spin up to 11 000 × g for 2 – 20 minutes.
3.	If the reagent appears to have spun dry in the device, the reagent is easily recovered by pipetting several times with approximately 50 µl buffer.
4.	Dilute the reagent with buffer to get a concentration of 1 mg/ml.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B2 Gyrolab instrument startup procedure

The following steps must be performed prior to start a Run on the Gyrolab instrument

- Turn on the instrument and laser (Chapter B2.1)
- Start Gyrolab Control (Chapter B2.2)
- Initialize the system (Chapter B2.3)
- Prime the system (Chapter B2.4)

The following solutions are required, refer to Chapter E1.2 for recipes

- Bioaffy Pump Liquid
- Bioaffy Wash Station Solution 1

B2.1 Turn on instrument and GL Degasser

NOTE: GL Degasser is only delivered with Gyrolab xP. In Gyrolab xPlore GL degasser is embedded.

Step	Action
1.	Switch on power. The power switches are located on the rear of the Gyrolab instrument and GL Degasser. For optimal performance turn on the instrument in advance before starting the Run: • Gyrolab instruments with serial number MW10010–MW10035, GW10036–GW10044, and GW10046–GW10065: 3 hours before starting a Run. • All other instruments: 30 minutes before starting a Run.
2.	• For systems without a LIF button the laser is turned on automatically. • For systems with a LIF button, check that the LIF button is in pressed down position. For LIF button position, refer to Chapter A2.2.1.

B2.2 Start Gyrolab Control software

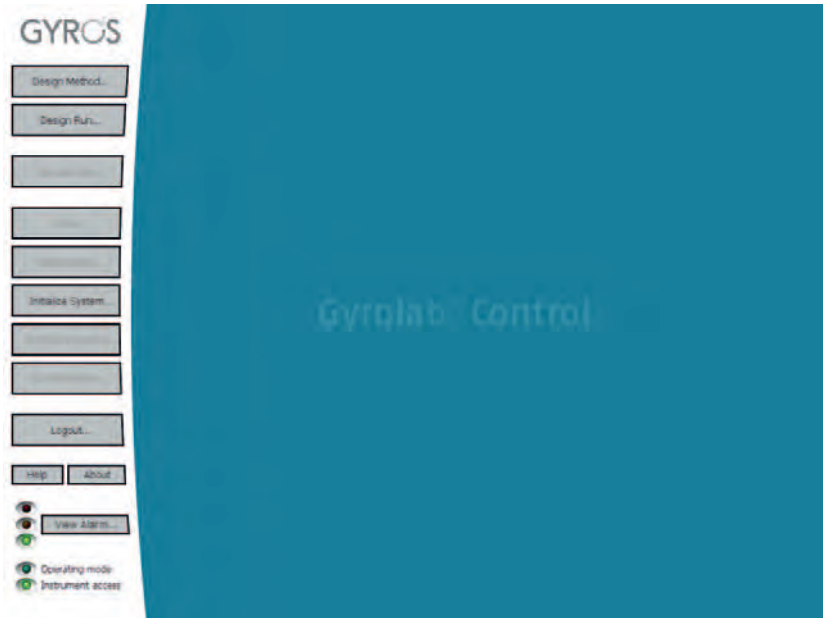
Gyrolab Control software consists of a server software and a client software. The server must be running before the client is started.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
1.	Start Gyrolab Server: • Click **Start:All Programs:Gyros:Server**. • **Gyrolab Instrument Log** is displayed and Gyrolab server icon appears on the task bar.
2.	Start Gyrolab Control software: • Select **Start:All Programs:Gyros:Client**.
3.	Enter user name and password in the **Login** dialog box and click **OK**. The user name and password is the same for all Gyrolab software. For further information on user and password administration, refer to Chapter F2.2.6. Password must be changed if requested by the software, for example when a new user logs in or if 90 days have passed since last password change. Password may also be changed when desired by the user: To change password: • Mark the check-box **Change Password.** • Enter current password in **Password** field, new password in **New Password** field and confirm new password in **Confirm Password** field. • Click **OK**. ***NOTE: User name and password are case sensitive.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
4.	Once logged in, the main screen will appear.

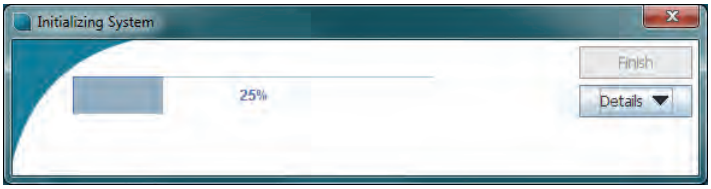


NOTE: *If no instrument access, restart the instrument.*

B2.3 Initialize the system

During initialization hardware tests of the instrument components are performed, for example robot arm movements, carousel rotation and CD stations vacuum.

Step	Action
1.	Close the instrument hatch if open. Click **Initialize System** on the Main menu. The **Initializing System** dialog box is displayed as initialization proceeds.



Details of the initialization can be viewed by clicking on the **Details** button.

NOTE: *To re-initialize the system, click on* **Logout** *in the Main menu. Choose* **Restart** *from the drop down menu in the* **Shut Down** *dialog, then click* **OK**.

2.	Click **Finish** when initialization is complete.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B2.4 Prime instrument

For optimal results it is important to prime the Gyrolab instrument before the first Run of the day. Gyrolab priming requires 15–20 minutes. Refer to Gyrolab Instrument Guide for priming instructions.

NOTE: ***If the instrument has not been used for at least two weeks extra priming must be performed. Refer to Gyrolab Instrument Guide.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B3 Design run

NOTE: There are two separate instructions, one for Gyrolab xP and one for Gyrolab xPlore.

This chapter describes the how to design runs in Gyrolab Control using the Wizard design type. For instructions on how to design a run using Custom design type, refer to Chapter H2.4. For instruction on how to use the optional add-on LIMS design type, refer to Chapter G1.2.

B3.1 Instructions for Gyrolab xP

B3.1.1 Wizard run design introduction

The two workflow Wizard and LIMS differ in run design. Design of runs are described in separate chapters Chapter B3.1.2 and Chapter B3. Sample preparations, run start and run finish procedure are the same for both workflow and will be described in chapters Chapter B4 – Chapter B6.

Step	Wizard Run
Create or Edit Run **Chapter B3.1.2**	• Select Wizard Run design type • Enter experimental parameters • Save Wizard Run
Sample List **Chapter B3.1.3**	Sample List generated by: • Gyrolab Control, or • manual editing (.xls), or
Prepare Run **Chapter B3.1.4**	• Select Wizard Run • Select Sample List • Enter experimental parameters • Set name and folder for result files • Set name and folder for reports • Generate Loading List

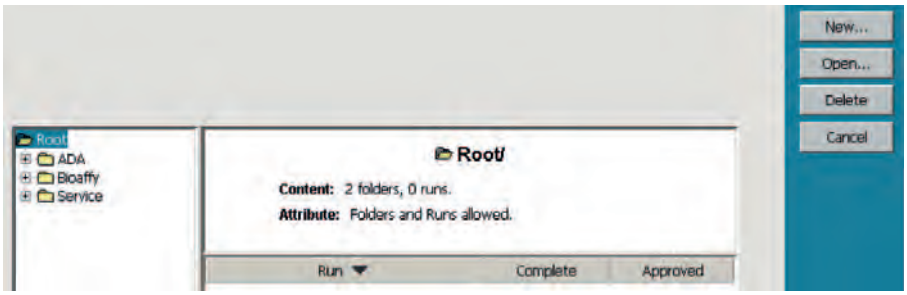
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B3.1.2 Create or edit a Wizard Run

There are three options available when setting up a new run:

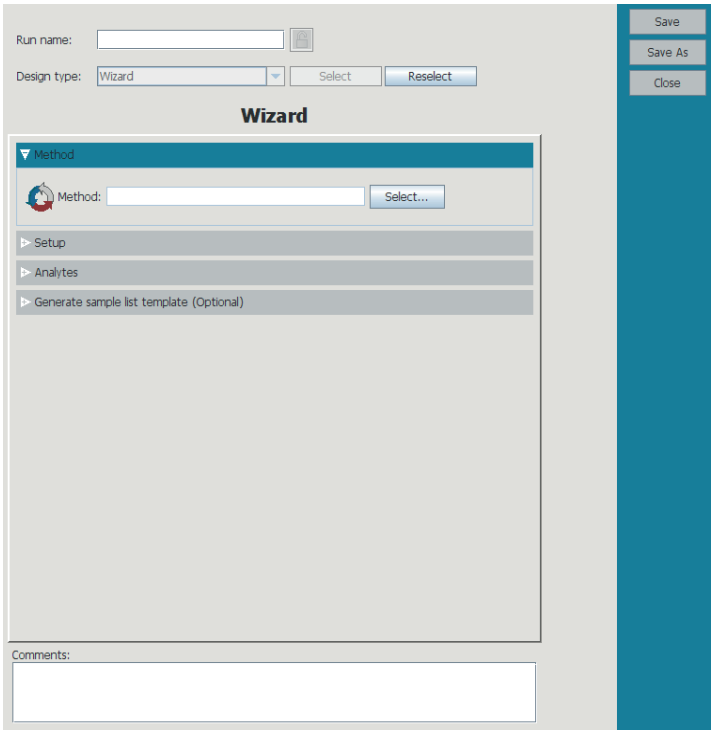
- Create a new Run, proceed with Chapter B3.1.2
- Edit an existing Run (use when similar but not identical experiment design is wanted), proceed with Chapter B3.1.2
- Use an existing Run (use when identical experiment design is wanted), go to Chapter B3.1.4.

Step	Action
1.	Click **Design Run** on the Main menu. The **Run** screen appears.



2.
- To create a new Run, click **New**. Enter a Run name in the **Run Name** field.
- To edit an existing Run, browse and select the desired Run and click **Open**.

3.
- Select Wizard in the **Design Type** list and click **Select**. The **Wizard** panel appears:

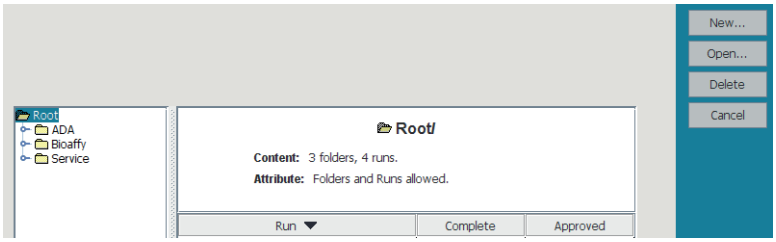


- To change design type, highlight the design type in the **Design Type** list and click **Reselect**.
- Comments for the Run can be made in the **Comments** window, for example what type of assays the run is intended for.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

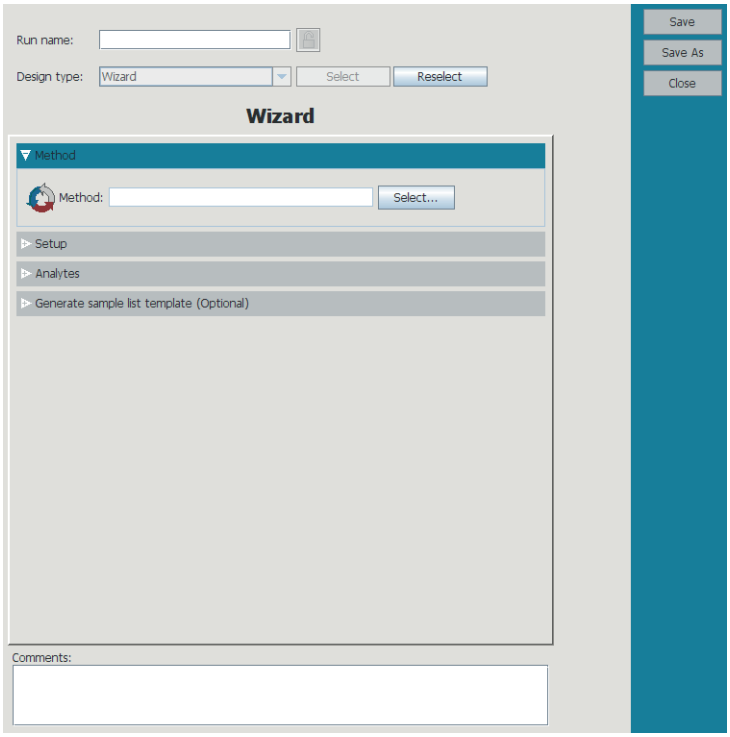
Step	Action

4. Click **Design Run** on the Main menu. The **Run** screen appears.



5.
- To create a new Run, click **New**. Enter a Run name in the **Run Name** field.
- To edit an existing Run, browse and select the desired Run and click **Open**.

6. Select Wizard in the **Design Type** list and click **Select**. The **Wizard** panel appears:

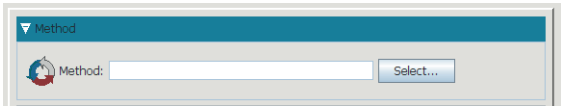


- To change design type, highlight the design type in the **Design Type** list and click **Reselect**.
- Comments for the Run can be made in the **Comments** window, for example what type of assays the run is intended for.

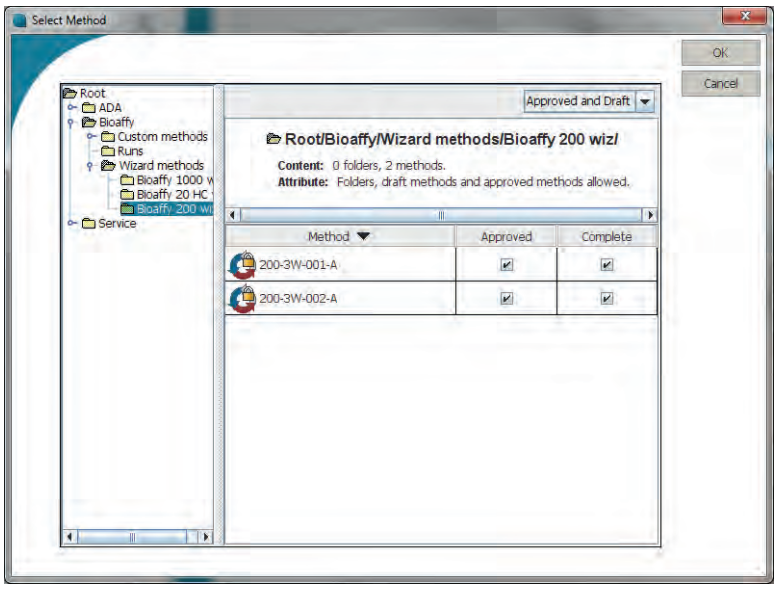
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

7. Select **Method** and click **Select**.

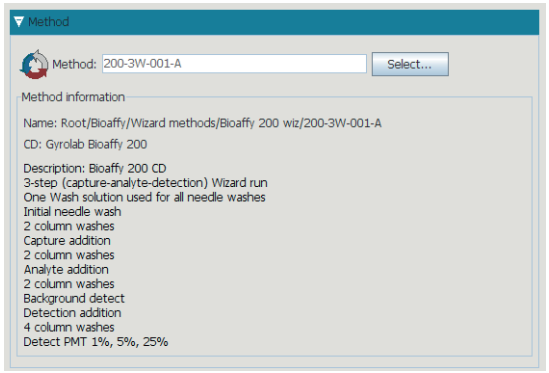


The **Select Method** dialog is opened.

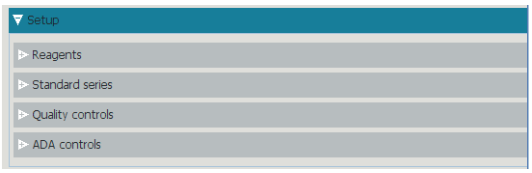


Browse and select desired Method. The selected Method must contain W in the name which indicates that it is designed for use with a Wizard run refer to Chapter A3.2 for more information.

Click **OK**. The selected method is added to the run design and method information is displayed.



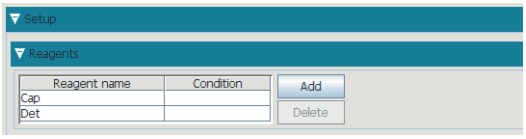
8. Select **Setup**.



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
9.	Select **Reagents**.

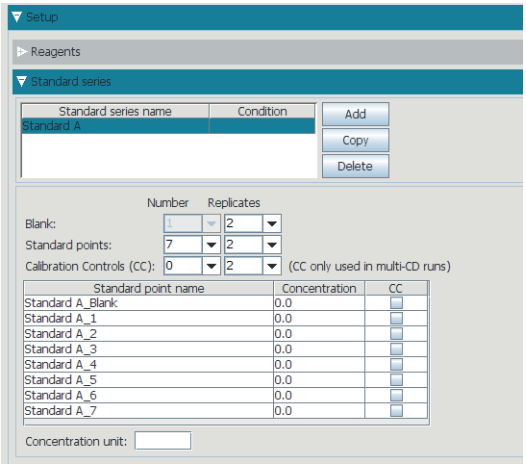
NOTE: ***The software will automatically add reagents to the design depending on selected method (1-step, 2-step, 3-step or 4-step). This can be edited by the user.***



- Specify **Name** for capture (Cap_) and detect (Det_) reagents. The **Condition** field is optional and can be used for additional information such as concentration value or matrix.
- Click **Add** to add more capture and detect reagents. Add and name one reagent in the software for each different reagent required for the design.
- Highlight reagent and click **Delete** to remove reagent.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
10.	Select **Standard series.**



- Specify **Name** for Standard series. **Condition** is optional and can be used for additional information such as Standard samples dilution buffer.
- Set **Replicates** for Blank samples. Highest number of replicates is 20.
- Set **Number** and **Replicates** for Standard series samples and Calibration Controls.
- Highest number of replicates is 8.
- For each Standard series sample, specify the **Concentration**.
- Specify unit in the **Concentration unit** text box.
- For multi-CD runs, the use of calibration controls is added by ticking **Calibration** check boxes for standard samples of choice. A marked check box means that for every CD that does not have a standard curve, calibration control(s) with concentration corresponding to that of the standard sample will be placed instead of the Standard series.

Additional functions:

- To add additional Standard series, click **Add**.
- To copy settings of one Standard series to a new Standard series, highlight desired Standard series and click **Copy**. The new Standard series can be edited and saved by a new name.
- Highlight Standard series and click **Delete** to remove a Standard series.

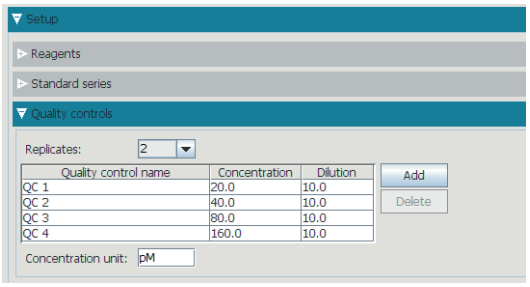
NOTE: ***Maximum 8 replicates for the same needle can be used in a Gyrolab Bioaffy 1000 CD.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

11. Select **Quality Control**. (This step is optional)

Quality Controls are samples with known concentration. Quality Controls may be used for quality control or when comparing results from different Runs and experiments.



- Set number of replicates in the Replicates list. Highest number of replicates is 8.
- Specify Quality control name, Concentration and Dilution for each Quality Control sample. The concentration value corresponds to Quality Control sample concentration before dilution. The dilution value corresponds to the dilution of the Quality Control sample. A value of 1 corresponds to an undiluted sample, Dilution values must be 1 or larger.
- Specify the unit in the Concentration unit text box.

NOTE: ***Note that the same unit must be used as used for the Standard series, refer to step 7.***

- Click Add for adding an additional Quality Control sample.
- Highlight Quality control sample and click Delete to remove.

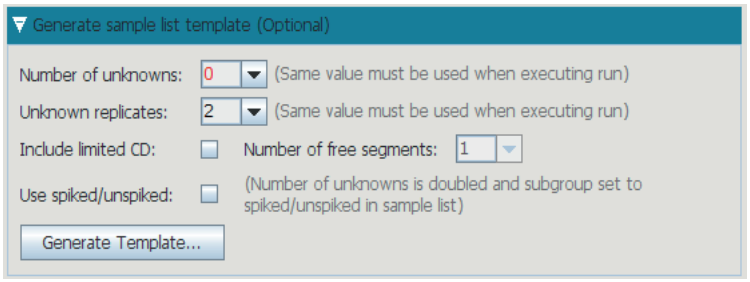
12.

- Add additional Analytes by clicking in the **Analytes** bar.
- Delete Analytes by clicking in the **Analyte:** bar.
- Add additional Experiments to an Analyte by clicking in the **Analyte:** bar.
- Delete Experiment by clicking in the **Experiment:** bar.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

13. Select **Generate Sample List template**.


Generate sample list template (Optional)
Number of unknowns:
0
(Same value must be used when executing run)
Unknown replicates:
2
(Same value must be used when executing run)
Include limited CD:
Number of free segments:
1
Use spiked/unspiked:
(Number of unknowns is doubled and subgroup set to spiked/unspiked in sample list)
Generate Template...

- Save the Run.
  - To save a new Wizard Run, click **Save**. Browse to select folder and click **Save**.
  - To save an edited Wizard Run, click **Save as**. Name the Run, browse to select folder and click **Save**. If **Save** is clicked the information on the original Run will be replaced with the edited information.
  - If any information added to the Wizard Run is incomplete or erratic an error message will be presented. The specified issues must be addressed before it is possible to save.
- Specify number of samples to be analyzed ("Unknown samples") in the **Number of unknowns** list.
- Specify number of sample replicates in the **Unknown replicates** list. Highest number of replicates are 8.
- If it is desired to use a CD that previously has been partially used, check **Include limited CD** and define number of available segments in the **Number of free segments** list.
- The **Use spiked/unspiked** check box is specific for the software module Gyrolab ADA Software. Refer to Chapter D2.2 for more information.
- Click **Generate template**.
- Browse to select Sample List location and click **Save**.

A Sample List is generated. The Sample List contains all necessary sample information defined in the run design. It also holds a suggestion for sample placement within the microplate.

NOTE: ***The procedure described in this step is the most convenient way to generate a Sample List. Sample Lists can created manually and automatically generated lists can be edited prior to run start, refer to Chapter B3.1.3. However, Gyros recommends using the automatically generated Sample Lists as this will reduce the risk or errors.***

14. Save the Run.

15. Click **Close** to finish the Design Run procedure.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B3.1.3 Sample List completion

A Sample List is designed to transfer important sample information from run design phase to run execution phase in Gyrolab Control. All samples types (Unknown samples, Standard samples, Quality Control samples, Calibration Control samples) defined in the Run are included in the Sample List. The automatically generated Sample list is a template, the final numbers of samples and replicates in a run are set when the Sample list is imported prior to run start, refer to Chapter B3.1.4.

Step Action

1. Open the Sample List (location defined in Chapter B3.1.2 step 13) in Microsoft Excel™. From row 8 and below one row represents one sample. Data is mandatory in columns labelled (**M**) and optional in columns labelled (**O**). Columns labelled (**N/A**) are not used. Example of automatically generated Sample List:

	A	B	C	D	E	F	G	H
1	Template	Sample3.0		Sample list info				
2	M=Manda	Sample M	MP96 PCR					
3	O=Option	Result File Name (O)						
4	N/A=Not /	Result File Path (O)						
5								
6								
7	Index (M)	Sample Ty	Sample Id	Sample Gr	Sample Su	Dilution F	MP Identi	Well (M)
8	#1	UNK	Sample 1				MP1	D1
9	#2	UNK	Sample 2				MP1	D2
10	#3	UNK	Sample 3				MP1	D3
11	#4	UNK	Sample 4				MP1	D4
12	#5	UNK	Sample 5				MP1	D5
13	#6	UNK	Sample 6				MP1	D6
14	#7	UNK	Sample 7				MP1	D7
15	#8	UNK	Sample 8				MP1	D8
16		BL	Standard A_Blank				MP1	A1
17		BL	Standard A_Blank				MP1	A2
18		STD	Standard A_1				MP1	A3
19		STD	Standard A_1				MP1	A4
20		STD	Standard A_2				MP1	A5
21		STD	Standard A_2				MP1	A6
22		STD	Standard A_3				MP1	A7
23		STD	Standard A_3				MP1	A8
24		STD	Standard A_4				MP1	A9
25		STD	Standard A_4				MP1	A10
26		STD	Standard A_5				MP1	A11
27		STD	Standard A_5				MP1	A12
28		STD	Standard A_6				MP1	B1
29		STD	Standard A_6				MP1	B2
30		STD	Standard A_7				MP1	B3
31		STD	Standard A_7				MP1	B4

2. Edit sample information as desired, make sure that data is in accordance with Table B3-1 on page 26.

- By default all samples and reagents of all types will be located on the same Sample Microplate. To have Unknown samples on the Sample Microplate and place all other sample types on a Reagent Microplate, delete all samples but unknowns from the generated Sample List. The software will automatically place deleted samples on a Reagent Microplate during Loading List generation, refer to Chapter B3.1.4.
- When evaluating results in Gyrolab Evaluator, refer to Chapter C, samples are sorted based on sample identity, group and subgroup, refer to Table B3-2 on page 27 for details. Statistics such as average, standard deviation and CV are available for these groups.

NOTE: Only edit rows 8 and below. Edits in other parts of the Sample list may cause the list to be incompatible with the run.

3. Save the edited Sample List.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Sample List item and column	Mandatory/ Optional	Information
Index **Column A**	Mandatory for Unknown samples, not used for other sample types.	The index is an identifier for Unknown samples (**UNK**). The form of the entry is predefined and the entries must be consecutively numbered: #1, #2, #3, and so on. ***NOTE: Do not use this column for Standard series, Quality Controls or Calibration Controls.***
Sample type **Column B**	Mandatory	• UNK for Unknown samples • QC for Quality Controls • CC for Calibration Controls • STD for Standard series • BL for Blanks
Sample Identity **Column C**	Mandatory	Enter Sample identity for all unknown samples. Sample identity is used as basis for statistical analysis in Gyrolab Evaluator software. Table B3-2, "Basis for sample statistics", on page 27 below.
Sample Group **Column D**	Optional	Sample Group is used to group samples with common properties. Sample group is used as basis for statistical analysis in Gyrolab Evaluator software.Table B3-2, "Basis for sample statistics", on page 27 below.
Sample Subgroup **Column E**	Optional	Sample Subgroup is used to subgroup samples within a Sample Group or Sample identity with common properties, for example samples given different treatment or from different time points. Sample subgroup is used as basis for statistical analysis in Gyrolab Evaluator software. Table B3-2, "Basis for sample statistics", on page 27 below.
Dilution Factor **Column F**	Optional for Unknown samples, not used for other sample types	
MP Identity **Column G**	Mandatory	A Microplate identity must be entered.
Well **Column H**	Mandatory	Identity of microplate well where the sample is located.

Table B3-1: Details for Sample List items

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Sample identity (Column C)	Sample group (Column D)	Sample subgroup (Column E)	Statistics based on
Used	Not used	Not used	Sample identity
Used	Used	Not used	Sample group
Used	Not used	Used	Sample identity and subgroup
Used	Used	Used	Sample group and subgroup

Table B3-2: Basis for sample statistics

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B3.1.4 Prepare Wizard Run

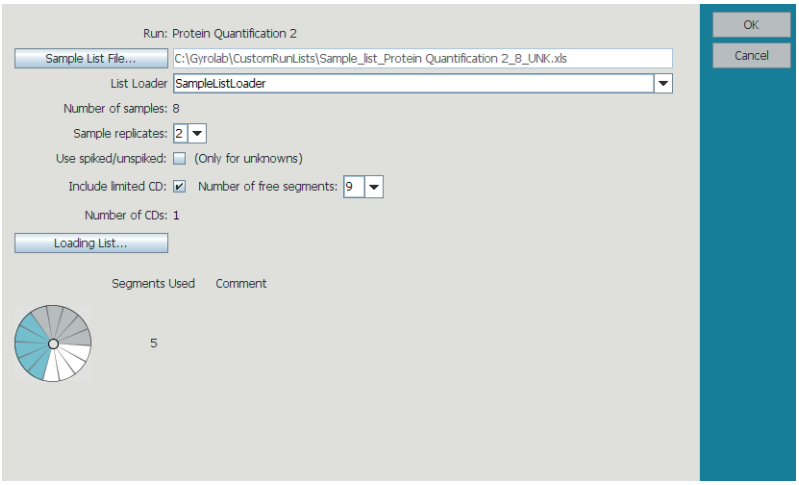
Step	Action

1. Click **Execute Run** on the Main menu.

2. Browse and select desired **Run** (as set in Chapter B3.1.4) from the list and click **OK**.

Runs that are not complete and thus not ready to execute, are marked with a zigzag line. More information is needed before the Run can be executed.

3. A screen is opened:



- To load a Sample List, click **Sample List file**, browse and select desired Sample List.
- **List Loader** file sets rules for how to import Sample list. Choose the **SampleList-Loader** option in the drop down menu.
- Number of Unknown samples will be displayed in the **Number of samples** field when the desired Sample List is loaded.
- The number of Unknown sample replicates was defined during run design (Chapter B3.1.2) and is displayed in the **Sample replicates** list. Sample replicate number can be changed compared what was defined during the run design.
- **Include limited CD** box is ticked if a partially used (limited) CD was included when the run was designed (Chapter B3.1.2). It will always be the first CD in the Run that is partially used. It is possible to remove limited CD or change number of available CD segments.

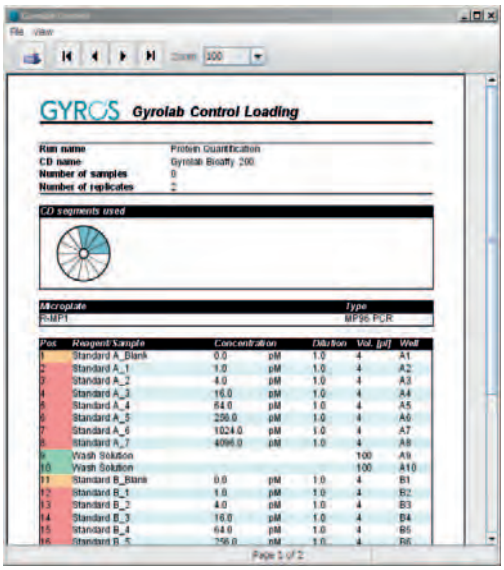
The CD and CD segment consumption is calculated based on number of samples and replicates. For all samples, position on the CD(s) is automatically randomized and distributed by the software. For multiple-CD runs: If Calibration Controls are used, these will be placed on each CD that do not have a corresponding Standard series.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

4. Click **Loading List**.

Gyrolab Control Loading screen is opened.



- **Gyrolab Control Loading** holds microplate loading information and is used when preparing microplates for a run. Name, concentration, volume, microplate and well position is included for all sample types. An overview of microplates with indication of used wells is also provided.
- Click **Printer** button to print the **Gyrolab Control Loading**.

TIP: ***Select* File: Export *to export the Loading list in PDF or text format. This is useful when printing from another computer is required.***

5. Close **Gyrolab Control Loading**.

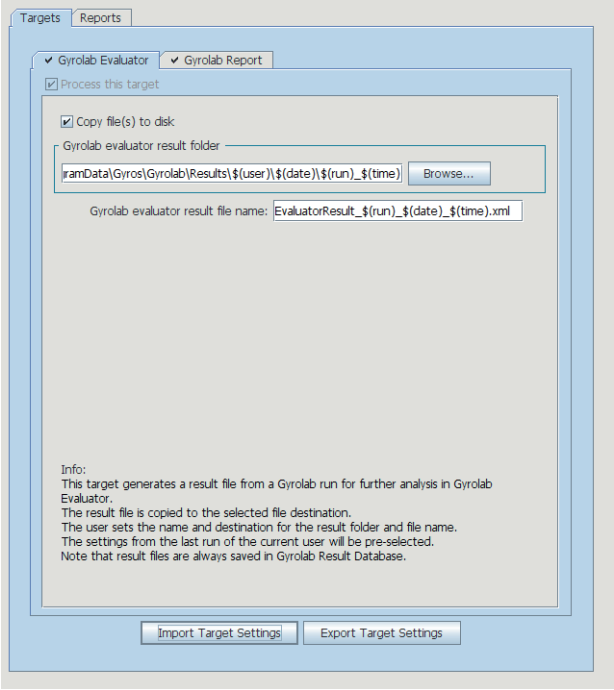
6. Click **OK**. A screen with two tabs, **Targets** and **Reports**, is opened.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

7. In the **Targets** tab, choose **Gyrolab Evaluator**.

Result files from the run are always saved in Gyrolab Result Database. To create local copies of the result files (optional), mark the check box **Copy file(s) to disc.**


Targets
Reports
Gyrolab Evaluator
Gyrolab Report
Process this target
Copy file(s) to disk
Gyrolab evaluator result folder
ramData\Gyros\Gyrolab\Results\$(user)\$(date)\$(run)_$(time)
Browse...
Gyrolab evaluator result file name:
EvaluatorResult_$(run)_$(date)_$(time).xml
Info:
This target generates a result file from a Gyrolab run for further analysis in Gyrolab Evaluator.
The result file is copied to the selected file destination.
The user sets the name and destination for the result folder and file name.
The settings from the last run of the current user will be pre-selected.
Note that result files are always saved in Gyrolab Result Database.
Import Target Settings
Export Target Settings

Files are saved to the location specified in **Gyrolab Evaluator result folder** field and with the name specified in **Gyrolab Evaluator result file name**. Settings are preserved from the user's last Run.

- To import default settings for **Gyrolab Evaluator result folder** and **Gyrolab Evaluator result file name**:
  - Click **Import Target Settings**.
  - In the **Import Settings** dialog, browse to `C:\ProgramData\Gyros\Gyrolab\Templates\Default Settings`, select **GyrolabEvaluatorTargetSettings.xml** and click **Import**.
- To customize settings for **Gyrolab Evaluator result folder** and **Gyrolab Evaluator result file name**:
  - To edit **Gyrolab Evaluator result folder**, click **Browse**. Browse and click **Select** to set new folder in the **Select folder** dialog.
  - To edit **Gyrolab Evaluator result file name**, click in the field and edit.

TIP: ***Macros can be used to construct file names and locations, refer to Chapter B3.1.5 for a list of available macros.***

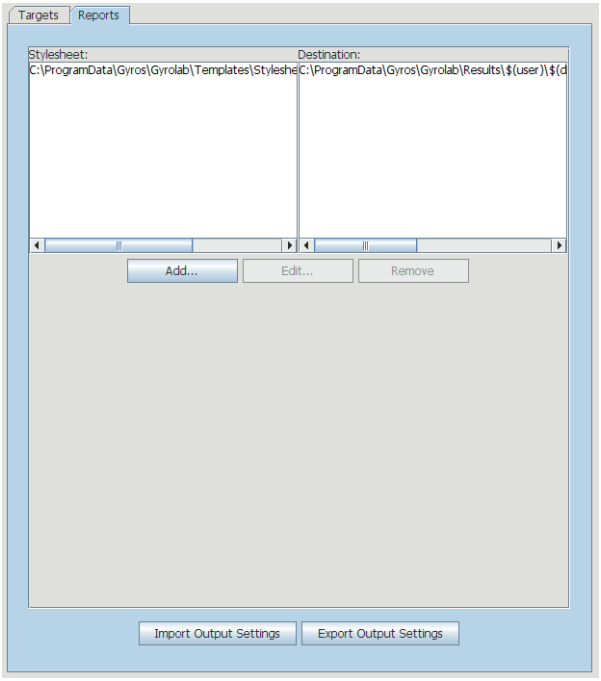
TIP: ***The settings in the Targets tab can be exported and imported, which enables settings to be shared between users, instruments and projects.***

8. The Targets tab, **Gyrolab Report** section contains settings specific for the software module Gyrolab Control Report and is only available if a licence for Gyrolab Control Report has been acquired. Refer to Chapter D4.2 for more information.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

9. Open **Reports** tab.



A report file that holds method information can be generated.

- To import default settings for report file **Stylesheet** and **Destination**:
  - Click **Import Output Settings**.
  - In the **Import Settings** dialog, browse to `C:\ProgramData\Gyros\Gyrolab\Templates\Default Settings`, select **ReportSettings.xml** and click **Import**.
- If no report file is wanted, select the file present in **Stylesheet** and click on **Remove** button.

TIP: ***Customized reports can be generated. Contact Gyros for information.***

10. Click **OK** and proceed to Chapter B4.1.1, sample and reagents preparations.

B3.1.5 Macros for creating names for folders and files

By using macros, unique names for results files and folders will be created automatically without having to change the settings for different Runs. A selection of macros are provided for this. Insert macros by typing them into folder and result file name fields.

Macro	Description
$(user)	Expands to the full user name.
$(run)	Expands to the Run name.
$(cdid)	Expands to the CD id, for example 1234567-123.
$(date)	Expands to the executed Run start date.
$(time)	Expands to the executed Run start time.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B3.2 Instructions for Gyrolab xPlore

B3.2.1 Wizard run design introduction

The two workflow Wizard and LIMS differ in run design. Design of runs are described in separate chapters Chapter B3.2 and Chapter B3. Sample preparations, run start and run finish procedure are the same for both workflow and will be described in chapters Chapter B4 – Chapter B6.

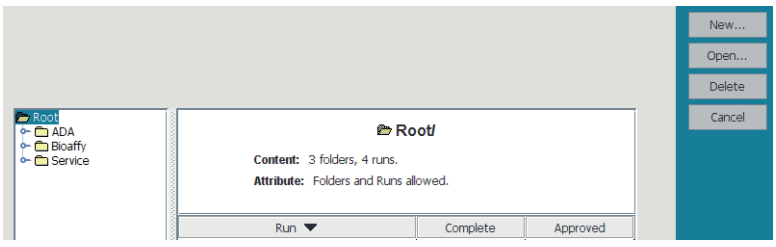
Step	Wizard Run
Create or Edit Run **Chapter B3.2.2**	• Select Wizard Run design type • Enter experimental parameters • Save Wizard Run
Sample List **Chapter B3.2.3**	Sample List generated by: • Gyrolab Control, or • manual editing (.xls), or
Prepare Run **Chapter B3.2.4**	• Select Wizard Run • Select Sample List • Enter experimental parameters • Set name and folder for result files • Set name and folder for reports • Generate Loading List

B3.2.2 Create or edit a Wizard Run

There are three options available when setting up a new run:

- Create a new Run, proceed with Chapter B3.2.2
- Edit an existing Run (use when similar but not identical experiment design is wanted), proceed with Chapter B3.2.2
- Use an existing Run (use when identical experiment design is wanted), go to Chapter B3.2.4.

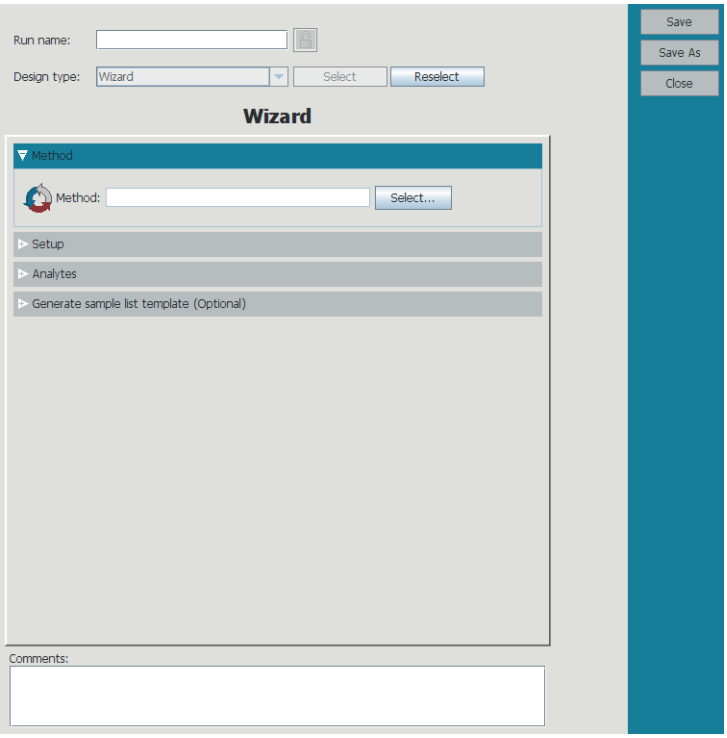
Step	Action
1.	Click **Design Run** on the Main menu. The **Run** screen appears.



2.
- To create a new Run, click **New**. Enter a Run name in the **Run Name** field.
- To edit an existing Run, browse and select the desired Run and click **Open**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

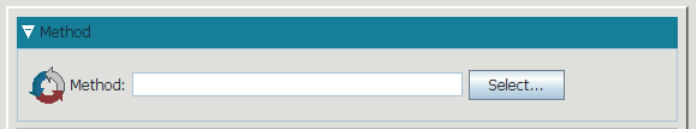
Step	Action
3.	• Select Wizard in the **Design Type** list and click **Select**. The **Wizard** panel appears:



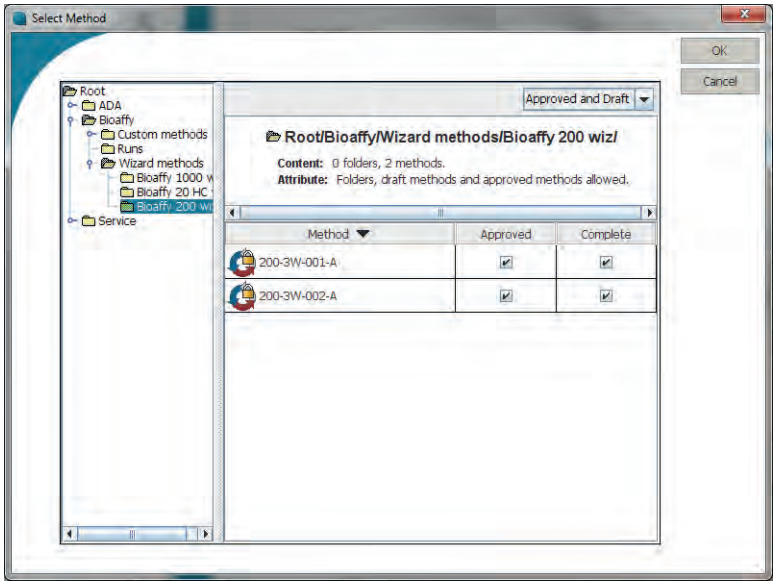
- To change design type, highlight the design type in the **Design Type** list and click **Reselect**.
- Comments for the Run can be made in the **Comments** window, for example what type of assays the run is intended for.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
4.	Select **Method** and click **Select**.

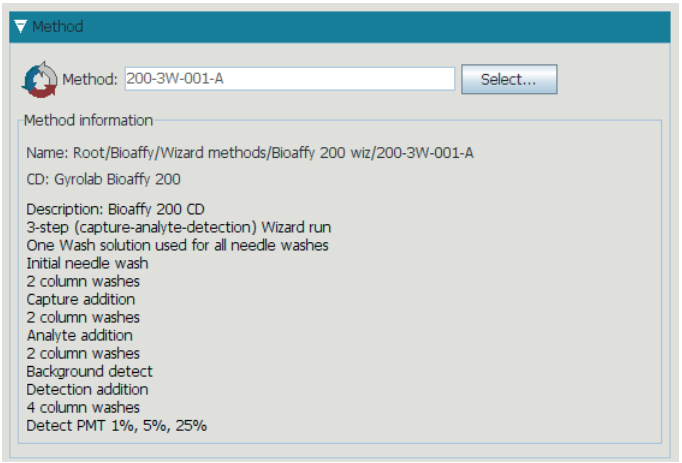


The **Select Method** dialog is opened.



Browse and select desired Method. The selected Method must contain W in the name which indicates that it is designed for use with a Wizard run refer to Chapter A3.2 for more information.

Click **OK**. The selected method is added to the run design and method information is displayed.



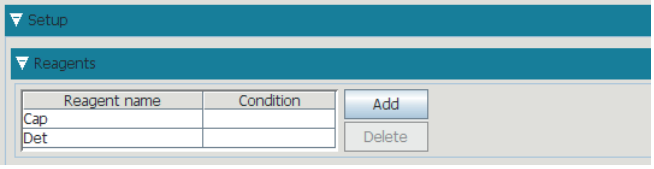
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

5. Select **Setup**.

6. Select **Reagents**.

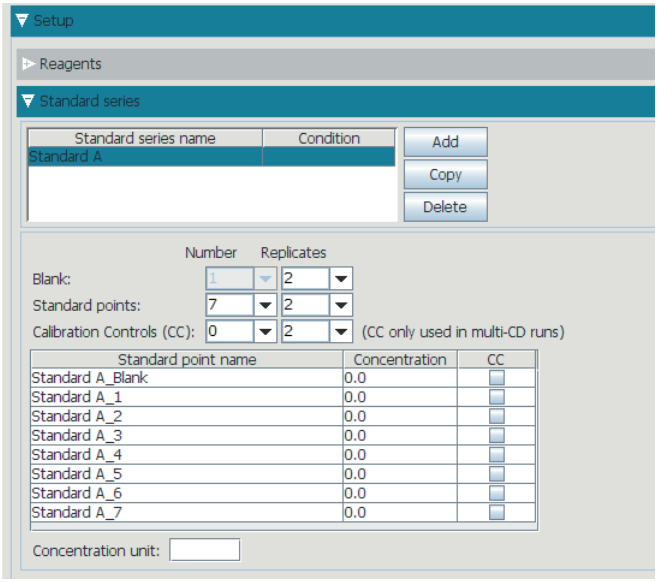
NOTE: ***The software will automatically add reagents to the design depending on selected method (1-step, 2-step, 3-step or 4-step). This can be edited by the user.***



- Specify **Name** for capture (Cap_) and detect (Det_) reagents. The **Condition** field is optional and can be used for additional information such as concentration value or matrix.
- Click **Add** to add more capture and detect reagents. Add and name one reagent in the software for each different reagent required for the design.
- Highlight reagent and click **Delete** to remove reagent.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
7.	Select **Standard series**.



- Specify **Name** for Standard series. **Condition** is optional and can be used for additional information such as Standard samples dilution buffer.
- Set **Replicates** for Blank samples. Highest number of replicates is 20.
- Set **Number** and **Replicates** for Standard series samples and Calibration Controls. Highest number of replicates is 8.
- For each Standard series sample, specify the **Concentration**.
- Specify unit in the **Concentration unit** text box.
- For multi-CD runs, the use of calibration controls is added by ticking **Calibration** check boxes for standard samples of choice. A marked check box means that for every CD that does not have a standard curve, calibration control(s) with concentration corresponding to that of the standard sample will be placed instead of the Standard series.

NOTE: ***Calibration controls are not applicable for the Gyrolab xPlore system. It is only applicable when designing a run for a Gyrolab xP system.***

Additional functions:

- To add additional Standard series, click **Add**.
- To copy settings of one Standard series to a new Standard series, highlight desired Standard series and click **Copy**. The new Standard series can be edited and saved by a new name.
- Highlight Standard series and click **Delete** to remove a Standard series.

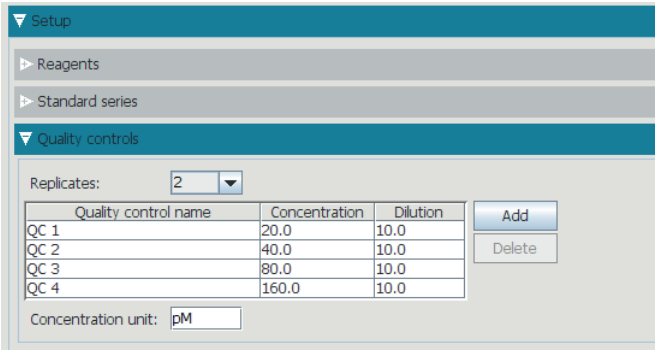
NOTE: ***Maximum 8 replicates for the same needle can be used in a Gyrolab Bioaffy 1000 CD.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

8. Select **Quality Control**. (This step is optional)

Quality Controls are samples with known concentration. Quality Controls may be used for quality control or when comparing results from different Runs and experiments.



- Set number of replicates in the **Replicates** list. Highest number of replicates is 8.
- Specify **Quality control name**, **Concentration** and **Dilution** for each Quality Control sample. The concentration value corresponds to Quality Control sample concentration before dilution. The dilution value corresponds to the dilution of the Quality Control sample. A value of 1 corresponds to an undiluted sample, Dilution values must be 1 or larger.
- Specify the unit in the **Concentration unit** text box.
  Note that the same unit must be used as used for the Standard series, refer to Step 7.
- Click **Add** for adding an additional Quality Control sample.
- Highlight Quality control sample and click **Delete** to remove.

9. The **ADA Control** section contains settings specific for the software module Gyrolab ADA Software. Refer to Chapter D2.2 for more information.

10. Select **Analytes.**

For each Run, one or more **Analytes** are defined.

For each Analyte one or more **Experiments** are defined. Experiment settings determine which Reagents, Standard series, Calibration Controls and Quality Controls (defined in Steps 6 to 8 above) to be used for the specific experiment.

To set up an Analyte with one Experiment, continue to next step.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

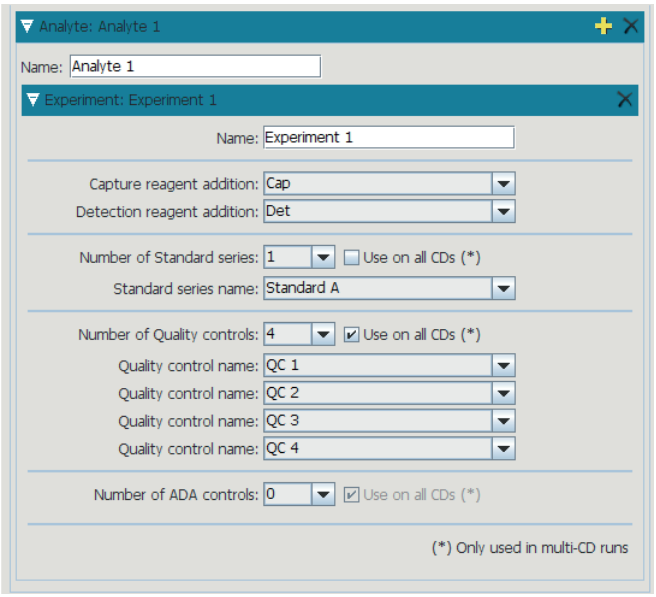
Step	Action

11.

- Select **Analyte: Analyte 1**. Enter a name for the Analyte in the **Name** text field.
- Select **Experiment: Experiment 1**. Enter a name for the Experiment in the **Name** text field.
- Select Capture reagent(s) from the **Capture reagent addition** list. Only Capture reagents specified in step 8 are available.
- Select Detection reagent(s) from the **Detection reagent addition** list. Only Detect reagents specified in step 8 are available.
- Select number of Standard series in the **Number of Standard series** list.
- For multi-CD runs: Tick **Use on all CDs** to place Standard series on all CDs included in the Run. This is only applicable for the Gyrolab xP system.
  - When **Use on all CDs** is ticked, unknown samples will be quantified against Standard series on the same CD. One analysis per CD will be created.
  - If **Use on all CDs** is not ticked, all unknown samples are quantified against the same Standard series.

NOTE: ***Instead of Standard series on all CDs, Calibration Controls can be used. Refer to step 7. This is not applicable for the Gyrolab xPlore system.***

- Select Standard series in the **Standard series name** list. Only Standard series specified in step 7 are available.
- Select number of Quality Controls in the **Number of Quality controls** list.
- For multi-CD runs: Tick **Use on all CDs** to place Quality Controls on all CDs included in the Run.
  - If **Use on all CDs** is selected, the Quality Controls samples will be applied on all CDs included in the Run.
  - If **Use on all CDs** is not selected, the Quality Controls samples will be applied on one CD even if the experiment is included on several CDs.
- Select Quality Controls in the **Quality control name** list(s). Only Quality Controls specified in step 8 are available.
- The **Number of ADA controls** field is specific for and only used with the software module Gyrolab ADA Software. Refer to Chapter D2.2 for more information.


Analyte: Analyte 1
Name: Analyte 1
Experiment: Experiment 1
Name: Experiment 1
Capture reagent addition: Cap
Detection reagent addition: Det
Number of Standard series: 1
Use on all CDs (*)
Standard series name: Standard A
Number of Quality controls: 4
Use on all CDs (*)
Quality control name: QC 1
Quality control name: QC 2
Quality control name: QC 3
Quality control name: QC 4
Number of ADA controls: 0
Use on all CDs (*)
(*) Only used in multi-CD runs

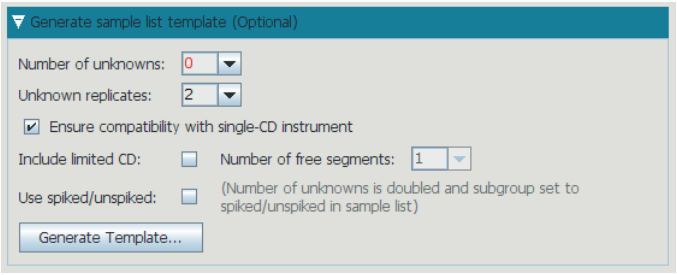
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
12.	• Add additional Analytes by clicking in the **Analytes** bar. • Delete Analytes by clicking in the **Analyte:** bar. • Add additional Experiments to an Analyte by clicking in the **Analyte:** bar. • Delete Experiment by clicking in the **Experiment:** bar.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

13. Select **Generate Sample List template**.



- Save the Run.
  - To save a new Wizard Run, click **Save**. Browse to select folder and click **Save**.
  - To save an edited Wizard Run, click **Save as**. Name the Run, browse to select folder and click **Save**. If **Save** is clicked the information on the original Run will be replaced with the edited information.
  - If any information added to the Wizard Run is incomplete or erratic an error message will be presented. The specified issues must be addressed before it is possible to save.
- Specify number of samples to be analyzed ("Unknown samples") in the **Number of unknowns** list.
- Specify number of sample replicates in the **Unknown replicates** list. Highest number of replicates are 8.
- **Ensure compatibility with single-CD instrument** checkbox. Purpose of this function is to help the user to ensure that the run can be executed on a single CD instrument by limiting the 'Number of unknowns'-dropbox to not exceed the number of structure on the CD. If the checkbox is checked. Then the dropbox is limited to one CD. If not checked the dropbox is limited to 5 CDs.

  Default values for the checkbox are:
  - If system is initialized:
    - it will be checked if the client is connected to a Gyrolab xPlore system.
    - Unchecked if connected to Gyrolab xP system.
  - If the system is not initiated:
    - a dialog will appear informing the user that configuration is unknown and the checkbox is unchecked.
- If it is desired to use a CD that previously has been partially used, check **Include limited CD** and define number of available segments in the **Number of free segments** list.
- The **Use spiked/unspiked** check box is specific for the software module Gyrolab ADA Software. Refer to Chapter D2.2 for more information.
- Click **Generate template**.
- Browse to select Sample List location and click **Save**.

A Sample List is generated. The Sample List contains all necessary sample information defined in the run design. It also holds a suggestion for sample placement within the microplate.

NOTE: ***The procedure described in this step is the most convenient way to generate a Sample List. Sample Lists can created manually and automatically generated lists can be edited prior to run start, refer to Chapter B3.2.3. However, Gyros recommends using the automatically generated Sample Lists as this will reduce the risk or errors.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
14.	Save the Run.
15.	Click **Close** to finish the Design Run procedure.

B3.2.3 Sample List completion

A Sample List is designed to transfer important sample information from run design phase to run execution phase in Gyrolab Control. All samples types (Unknown samples, Standard samples, Quality Control samples, Calibration Control samples) defined in the Run are included in the Sample List. The automatically generated Sample list is a template, the final numbers of samples and replicates in a run are set when the Sample list is imported prior to run start, refer to Chapter B3.2.4.

Step	Action
1.	Open the Sample List (location defined in Chapter B3.2.2 step 10) in Microsoft Excel™. From row 8 and below one row represents one sample. Data is mandatory in columns labelled (**M**) and optional in columns labelled (**O**). Columns labelled (**N/A**) are not used. Example of automatically generated Sample List:

	A	B	C	D	E	F	G	H
1	Template	Sample3.0		Sample list info				
2	M=Manda	Sample M	MP96 PCR					
3	O=Option	Result File Name (O)						
4	N/A=Not /	Result File Path (O)						
5								
6								
7	Index (M)	Sample Ty	Sample Id	Sample Gr	Sample Su	Dilution F	MP Identi	Well (M)
8	#1	UNK	Sample 1				MP1	D1
9	#2	UNK	Sample 2				MP1	D2
10	#3	UNK	Sample 3				MP1	D3
11	#4	UNK	Sample 4				MP1	D4
12	#5	UNK	Sample 5				MP1	D5
13	#6	UNK	Sample 6				MP1	D6
14	#7	UNK	Sample 7				MP1	D7
15	#8	UNK	Sample 8				MP1	D8
16		BL	Standard A_Blank				MP1	A1
17		BL	Standard A_Blank				MP1	A2
18		STD	Standard A_1				MP1	A3
19		STD	Standard A_1				MP1	A4
20		STD	Standard A_2				MP1	A5
21		STD	Standard A_2				MP1	A6
22		STD	Standard A_3				MP1	A7
23		STD	Standard A_3				MP1	A8
24		STD	Standard A_4				MP1	A9
25		STD	Standard A_4				MP1	A10
26		STD	Standard A_5				MP1	A11
27		STD	Standard A_5				MP1	A12
28		STD	Standard A_6				MP1	B1
29		STD	Standard A_6				MP1	B2
30		STD	Standard A_7				MP1	B3
31		STD	Standard A_7				MP1	B4

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

2. Edit sample information as desired, make sure that data is in accordance with Table B3-3 on page 42.

- By default all samples and reagents of all types will be located on the same Sample Microplate. To have Unknown samples on the Sample Microplate and place all other sample types on a Reagent Microplate, delete all samples but unknowns from the generated Sample List. The software will automatically place deleted samples on a Reagent Microplate during Loading List generation, refer to Chapter B3.2.4.
- When evaluating results in Gyrolab Evaluator, refer to Chapter C, samples are sorted based on sample identity, group and subgroup, refer to Table B3-4 on page 43 for details. Statistics such as average, standard deviation and CV are available for these groups.

NOTE: Only edit rows 8 and below. Edits in other parts of the Sample list may cause the list to be incompatible with the run.

3. Save the edited Sample List.

Sample List item and column	Mandatory/ Optional	Information
Index **Column A**	Mandatory for Unknown samples, not used for other sample types.	The index is an identifier for Unknown samples (**UNK**). The form of the entry is predefined and the entries must be consecutively numbered: #1, #2, #3, and so on. ***NOTE: Do not use this column for Standard series, Quality Controls or Calibration Controls.***
Sample type **Column B**	Mandatory	• UNK for Unknown samples • QC for Quality Controls • CC for Calibration Controls • STD for Standard series • BL for Blanks
Sample Identity **Column C**	Mandatory	Enter Sample identity for all unknown samples. Sample identity is used as basis for statistical analysis in Gyrolab Evaluator software. Table B3-4, "Basis for sample statistics", on page 43 below.
Sample Group **Column D**	Optional	Sample Group is used to group samples with common properties. Sample group is used as basis for statistical analysis in Gyrolab Evaluator software.Table B3-4, "Basis for sample statistics", on page 43 below.

Table B3-3: Details for Sample List items

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Sample List item and column	Mandatory/ Optional	Information
Sample Subgroup **Column E**	Optional	Sample Subgroup is used to subgroup samples within a Sample Group or Sample identity with common properties, for example samples given different treatment or from different time points. Sample subgroup is used as basis for statistical analysis in Gyrolab Evaluator software. Table B3-4, "Basis for sample statistics", on page 43 below.
Dilution Factor **Column F**	Optional for Unknown samples, not used for other sample types	
MP Identity **Column G**	Mandatory	A Microplate identity must be entered.
Well **Column H**	Mandatory	Identity of microplate well where the sample is located.

Table B3-3: Details for Sample List items

Sample identity (Column C)	Sample group (Column D)	Sample subgroup (Column E)	Statistics based on
Used	Not used	Not used	Sample identity
Used	Used	Not used	Sample group
Used	Not used	Used	Sample identity and subgroup
Used	Used	Used	Sample group and subgroup

Table B3-4: Basis for sample statistics

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B3.2.4 Prepare Wizard Run

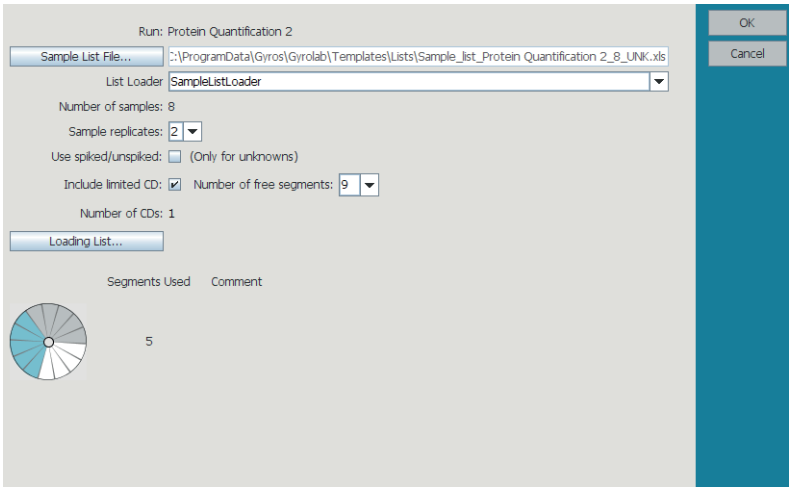
Step	Action

1. Click **Execute Run** on the Main menu.

2. Browse and select desired **Run** (as set in Chapter B3.2.4) from the list and click **OK**.

Runs that are not complete and thus not ready to execute, are marked with a zigzag line. More information is needed before the Run can be executed.

3. A screen is opened:



- To load a Sample List, click **Sample List file**, browse and select desired Sample List.
- **List Loader** file sets rules for how to import Sample list. Choose the **SampleList-Loader** option in the drop down menu.
- Number of Unknown samples will be displayed in the **Number of samples** field when the desired Sample List is loaded.
- The number of Unknown sample replicates was defined during run design (Chapter B3.2.2) and is displayed in the **Sample replicates** list. Sample replicate number can be changed compared what was defined during the run design.
- **Include limited CD** box is ticked if a partially used (limited) CD was included when the run was designed (Chapter B3.2.2). It will always be the first CD in the Run that is partially used. It is possible to remove limited CD or change number of available CD segments.

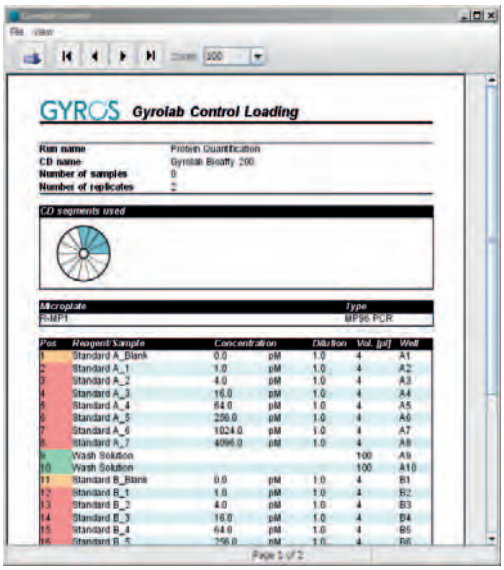
The CD and CD segment consumption is calculated based on number of samples and replicates. For all samples, position on the CD(s) is automatically randomized and distributed by the software. For multiple-CD runs: If Calibration Controls are used, these will be placed on each CD that do not have a corresponding Standard series.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

4. Click **Loading List**.

Gyrolab Control Loading screen is opened.



- **Gyrolab Control Loading** holds microplate loading information and is used when preparing microplates for a run. Name, concentration, volume, microplate and well position is included for all sample types. An overview of microplates with indication of used wells is also provided.
- Click **Printer** button to print the **Gyrolab Control Loading**.

TIP: ***Select* File: Export *to export the Loading list in PDF or text format. This is useful when printing from another computer is required.***

5. Close **Gyrolab Control Loading**.

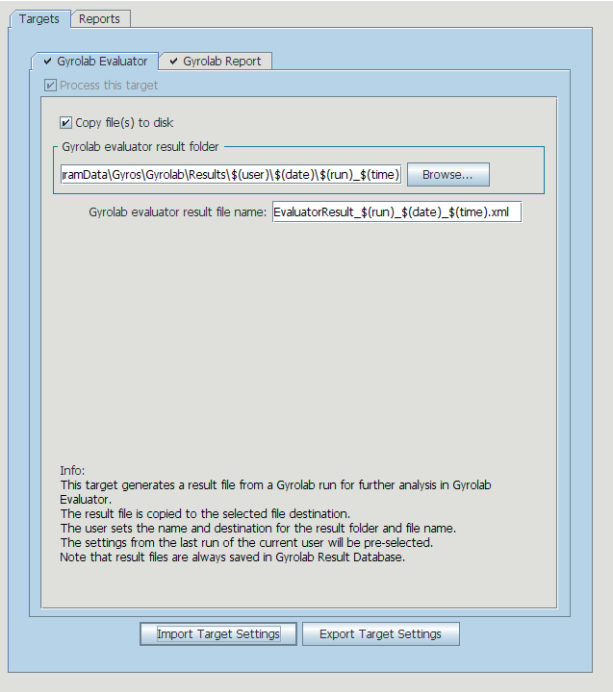
6. Click **OK**. A screen with two tabs, **Targets** and **Reports**, is opened.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

7. In the **Targets** tab, choose **Gyrolab Evaluator**.

Result files from the run are always saved in Gyrolab Result Database. To create local copies of the result files (optional), mark the check box **Copy file(s) to disc.**


Targets
Reports
Gyrolab Evaluator
Gyrolab Report
Process this target
Copy file(s) to disk
Gyrolab evaluator result folder
ramData\Gyros\Gyrolab\Results\$(user)\$(date)\$(run)_$(time)
Browse...
Gyrolab evaluator result file name:
EvaluatorResult_$(run)_$(date)_$(time).xml
Info:
This target generates a result file from a Gyrolab run for further analysis in Gyrolab Evaluator.
The result file is copied to the selected file destination.
The user sets the name and destination for the result folder and file name.
The settings from the last run of the current user will be pre-selected.
Note that result files are always saved in Gyrolab Result Database.
Import Target Settings
Export Target Settings

Files are saved to the location specified in **Gyrolab Evaluator result folder** field and with the name specified in **Gyrolab Evaluator result file name**. Settings are preserved from the user's last Run.

- To import default settings for **Gyrolab Evaluator result folder** and **Gyrolab Evaluator result file name**:
  - Click **Import Target Settings**.
  - In the **Import Settings** dialog, browse to `C:\ProgramData\Gyros\Gyrolab\Templates\Default Settings`, select **GyrolabEvaluatorTargetSettings.xml** and click **Import**.
- To customize settings for **Gyrolab Evaluator result folder** and **Gyrolab Evaluator result file name**:
  - To edit **Gyrolab Evaluator result folder**, click **Browse**. Browse and click **Select** to set new folder in the **Select folder** dialog.
  - To edit **Gyrolab Evaluator result file name**, click in the field and edit.

TIP: ***Macros can be used to construct file names and locations, refer to Chapter B3.2.5 for a list of available macros.***

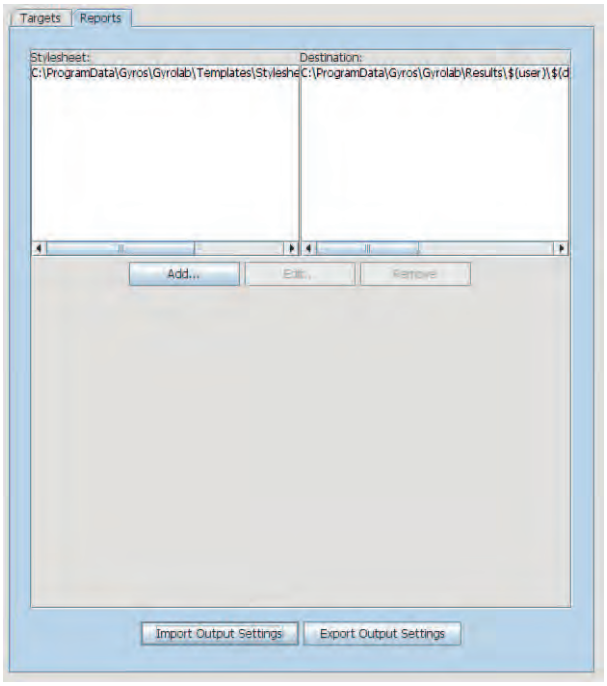
TIP: ***The settings in the Targets tab can be exported and imported, which enables settings to be shared between users, instruments and projects.***

8. The Targets tab, **Gyrolab Report** section contains settings specific for the software module Gyrolab Control Report and is only available if a licence for Gyrolab Control Report has been acquired. Refer to Chapter D4.2 for more information.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

9. Open **Reports** tab.



A report file that holds method information can be generated.

- To import default settings for report file **Stylesheet** and **Destination**:
  - Click **Import Output Settings**.
  - In the **Import Settings** dialog, browse to `C:\ProgramData\Gyros\Gyrolab\Templates\Default Settings`, select **ReportSettings.xml** and click **Import**.
- If no report file is wanted, select the file present in **Stylesheet** and click on **Remove** button.

TIP: ***Customized reports can be generated. Contact Gyros for information.***

10. Click **OK** and proceed to Chapter B4.1.1, sample and reagents preparations.

B3.2.5 Macros for creating names for folders and files

By using macros, unique names for results files and folders will be created automatically without having to change the settings for different Runs. A selection of macros are provided for this. Insert macros by typing them into folder and result file name fields.

Macro	Description
$(user)	Expands to the full user name.
$(run)	Expands to the Run name.
$(cdid)	Expands to the CD id, for example 1234567-123.
$(date)	Expands to the executed Run start date.
$(time)	Expands to the executed Run start time.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B4 Prepare samples and reagents

NOTE: There are two separate instructions, one for Gyrolab xP and one for Gyrolab xPlore.

This chapter describes sample and reagent preparation when working with Gyrolab Bioaffy CDs. For sample and reagent preparation for Gyrolab Mixing CDs, refer to Chapter D2.

Preparation of Capture and Detection reagents, Standard series, Calibration Controls, Quality Controls and Unknown samples for Gyrolab Bioaffy CDs and their loading into microplates is described in this chapter. Refer to Chapter A3.3 for more info on sample types. Minimum required reagent and sample volumes are specified in the Gyrolab Control Loading list, Chapter B3.1.4.

Gyros provides Rexxip™ buffers for reagent and sample dilution. Rexxip buffers are optimized for all types of applications and CDs and for a variety of molecules with different analytical properties. Suitable Rexxip buffer should be selected considering sample type and species, analyte and assay format. Refer to Product Information Sheet for Rexxip buffers for recommendations on buffer selection.

The following solutions and reagents are required

- PBS-T (for recipe, refer to Chapter E1.2)
- Capture and Detection reagents
- Standard Protein
- Rexxip buffer (Refer to Product information sheet for Rexxip buffers for recommendations on buffer selection)

B4.1 Instructions for Gyrolab xP

B4.1.1 Reagents and samples

B4.1.1.1 Capture reagent

1. Vortex Capture reagent stock solution gently
2. Dilute in PBS-T or Rexxip to working concentration (usually 700 nM, for an antibody this corresponds to 0.1 mg/ml). For minimum required reagent volumes, please refer to the Gyrolab Control Loading list, Chapter B3.1.4.

NOTE: Use fresh Capture reagent: Use new aliquots from the Capture reagent stock solution (kept in refrigerator or freezer) at least every week and prepare fresh dilutions of Capture reagent daily.

B4.1.1.2 Detection reagent

1. Vortex Detection reagent stock solution gently
2. Spin at 12 000 × g for 4 minutes to pellet any aggregates that may have formed during storage.
3. Dilute the detection reagent in Rexxip buffer (usually Rexxip F) to the optimal working concentration. Use a dark vial to minimize fluorophore exposure to light. Avoid pipetting from the bottom of the detection reagent stock tube to avoid transferring aggregates. Aggregates may affect the performance of the assay. For minimum required reagent volumes, please refer to the Gyrolab Control Loading list, Chapter B3.1.4.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

NOTE: Prepare fresh dilutions of Detection reagent daily.

B4.1.1.3 Standard series and Calibration Controls

Standard series samples and Calibration Controls are crucial parts of the experiment. They must be prepared and handled with care since errors during this process will affect all concentration values for the Unknown samples.

For minimum required volumes for Standard samples, please refer to the Gyrolab Control Loading list, Chapter B3.1.4.

1. Take a new vial from the freezer (or from other appropriate storage).
2. Reconstitute lyophilized standards for dilution according to their product data sheet.
3. Make serial dilutions of the Standard sample proteins in appropriate Rexxip buffer
4. Ensure sufficient mixing but do not shake.

NOTE: For the Standard series samples used as Calibration Controls one must prepare extra volume during dilution to ensure that the volume is sufficient for both the Standard series and Calibration Control. It is very important that the Standard series sample and Calibration Control are from the identical dilution. Note that identical Standard/Calibration Control concentrations are distributed to separate microplate wells for each CD in experiments using more than one CD.

B4.1.1.4 Unknown samples and Quality Controls

Quality Controls are prepared in the same manner as Unknown samples.

Step	Action
1.	Thaw sample vials completely on ice. ***NOTE: Avoid repeated freeze and thaw cycles of samples. Aliqout samples before freezing.***
2.	Vortex the vials gently.
3.	For serum and plasma samples and all other samples that may contain particulate matter with cell debris or pellet, centrifuge 3000 × g for 15 min at 8 °C.
4.	Dilute samples to concentration specified in the Loading List using appropriate Rexxip buffer. The dilution factor needs to be optimized for each analyte, assay format and matrix. Dilution should be made so that buffer characteristics are as similar as possible for all samples.
5.	Ensure sufficient mixing. Use microtubes for mixing of small samples volumes.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B4.1.2 Load microplates

Step	Action
1.	Add reagents, samples and solutions to microplates. Sample volume, microplate name and microplate well is specified in Gyrolab Control Loading list, Chapter B3.1.4. • Capture reagent • Detection reagent • Unknown samples • Quality Controls • Standard series samples • Calibration Controls • Blanks • Wash solutions (For recipe, refer to Chapter E1)
2.	Cover filled wells temporarily during preparation of microplates (for example with PCR lids) to avoid evaporation.
3.	When a microplate is loaded, apply Microplate Foil using a Microplate Foil Adapter. Instruction is supplied together with Microplate Foil Adapter.
4.	Centrifuge microplates at 3000 × g for two minutes. This is done to eliminate bubbles in the microplate wells and to ensure that the samples are at the bottom of the wells. Examine microplates after centrifugation to make sure that no bubbles are present.

NOTE: ***Do not stack microplate foil-sealed microplates on top of each other. The microplate foil may get perforated which may cause evaporation from wells.***

NOTE: ***Contamination risk! Microplate wells must not contain more than 100 µl of any solution. Needles are not washed higher than 1 cm.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B4.2 Instructions for Gyrolab xPlore

B4.2.1 Reagents and samples

B4.2.1.1 Capture reagent

1. Vortex Capture reagent stock solution gently
2. Dilute in PBS-T or Rexxip to working concentration (usually 700 nM, for an antibody this corresponds to 0.1 mg/ml). For minimum required reagent volumes, please refer to the Gyrolab Control Loading list, Chapter B3.2.4.

*NOTE: **Use fresh Capture reagent: Use new aliquots from the Capture reagent stock solution (kept in refrigerator or freezer) at least every week and prepare fresh dilutions of Capture reagent daily.***

B4.2.1.2 Detection reagent

1. Vortex Detection reagent stock solution gently
2. Spin at 12 000 × g for 4 minutes to pellet any aggregates that may have formed during storage.
3. Dilute the detection reagent in Rexxip buffer (usually Rexxip F) to the optimal working concentration. Use a dark vial to minimize fluorophore exposure to light. Avoid pipetting from the bottom of the detection reagent stock tube to avoid transferring aggregates. Aggregates may affect the performance of the assay. For minimum required reagent volumes, please refer to the Gyrolab Control Loading list, Chapter B3.2.4.

*NOTE: **Prepare fresh dilutions of Detection reagent daily.***

B4.2.1.3 Standard series

Standard series samples are a crucial part of the experiment. They must be prepared and handled with care since errors during this process will affect all concentration values for the Unknown samples.

For minimum required volumes for Standard samples, please refer to the Gyrolab Control Loading list, Chapter B3.2.4.

1. Take a new vial from the freezer (or from other appropriate storage).
2. Reconstitute lyophilized standards for dilution according to their product data sheet.
3. Make serial dilutions of the Standard sample proteins in appropriate Rexxip buffer
4. Ensure sufficient mixing but do not shake.

B4.2.1.4 Unknown samples and Quality Controls

Quality Controls are prepared in the same manner as Unknown samples.

Step	Action
1.	Thaw sample vials completely on ice. *NOTE: **Avoid repeated freeze and thaw cycles of samples. Aliqout samples before freezing.***
2.	Vortex the vials gently.
3.	For serum and plasma samples and all other samples that may contain particulate matter with cell debris or pellet, centrifuge 3000 × g for 15 min at 8 °C.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
4.	Dilute samples to concentration specified in the Loading List using appropriate Rexxip buffer. The dilution factor needs to be optimized for each analyte, assay format and matrix. Dilution should be made so that buffer characteristics are as similar as possible for all samples.
5.	Ensure sufficient mixing. Use microtubes for mixing of small samples volumes.

B4.2.2 Load microplates

Step	Action
1.	Add reagents, samples and solutions to microplates. Sample volume, microplate name and microplate well is specified in Gyrolab Control Loading list, Chapter B3.2.4. • Capture reagent • Detection reagent • Unknown samples • Quality Controls • Standard series samples • Blanks • Wash solutions (For recipe, refer to Chapter E1)
2.	Cover filled wells temporarily during preparation of microplates (for example with PCR lids) to avoid evaporation.
3.	When a microplate is loaded, apply Microplate Foil using a Microplate Foil Adapter. Instruction is supplied together with Microplate Foil Adapter.
4.	Centrifuge microplates at 3000 × g for two minutes. This is done to eliminate bubbles in the microplate wells and to ensure that the samples are at the bottom of the wells. Examine microplates after centrifugation to make sure that no bubbles are present.

NOTE: ***Do not stack microplate foil-sealed microplates on top of each other. The microplate foil may get perforated which may cause evaporation from wells.***

NOTE: ***Contamination risk! Microplate wells must not contain more than 100 µl of any solution. Needles are not washed higher than 1 cm.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B5 Start Run procedures

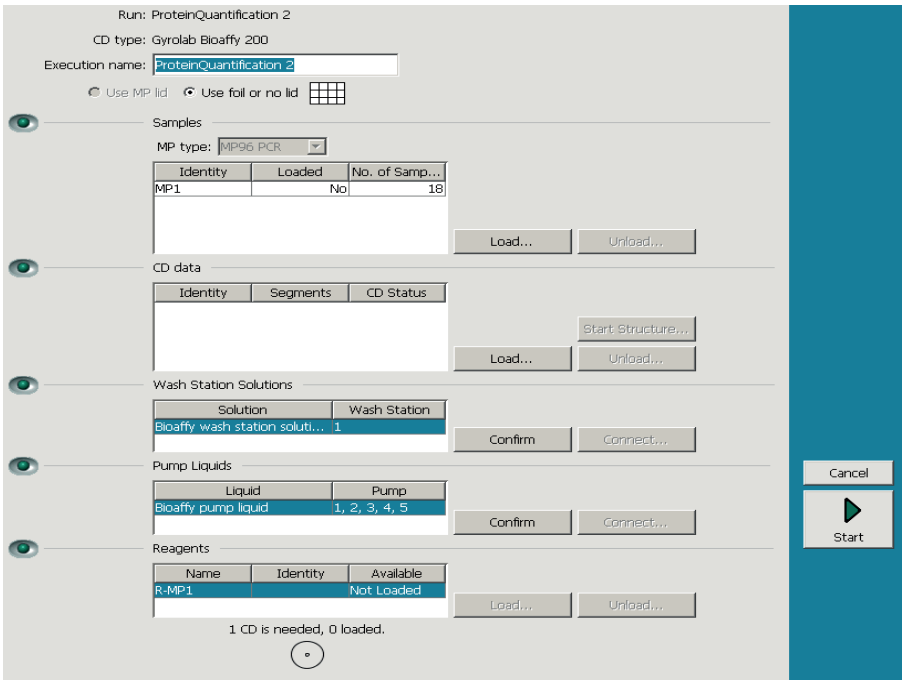
NOTE: ***There are two separate instructions, one for Gyrolab xP and one for Gyrolab xPlore.***

B5.1 Instructions for Gyrolab xP

B5.1.1 Load Gyrolab instrument

Before starting the instrument loading procedure, ensure that run preparations and sample and reagent preparations have been performed according to Chapter B3 and Chapter B4.

Step	Action
1.	The following screen should be shown after the clicking **OK** in the last step in Chapter B3.1.4.



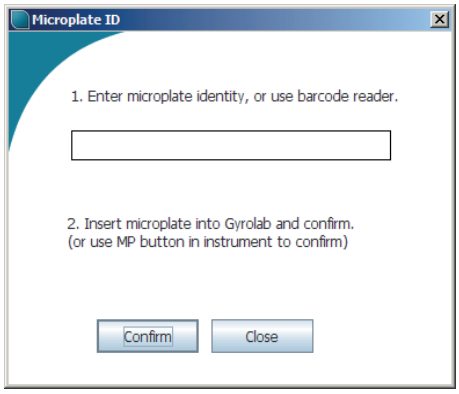
The screen is a check list for the loading steps. Upon completion of each step, the corresponding green LED on the left panel is lit. A Run cannot be started until all LEDs are lit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B5.1.1.1 Load sample microplates

Step	Action

1. Click **Load** in the **Samples** section. The **Microplate ID** dialog appears:


Microplate ID
1. Enter microplate identity, or use barcode reader.
2. Insert microplate into Gyrolab and confirm.
(or use MP button in instrument to confirm)
Confirm
Close

- Either scan the barcode ID, or click **Enter ID Manually** and enter microplate ID as stated in the Loading List.*
- Insert sample microplate in loading position (Chapter A2.2.1).
- Click **Confirm**. The microplate ID will appear in the list on screen.

2. Repeat for each sample microplate until all sample microplates are loaded.

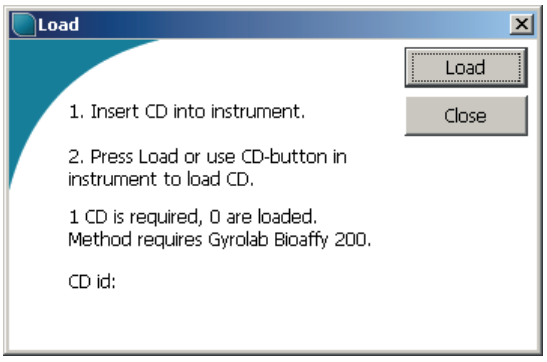
* Ensure the BCR is configured so that **Enter** or **Carriage Return** is not added when scanning the identity of a MP

B5.1.2 Load CDs

Step	Action

1. Put CDs in room temperature for 30 minutes (in the unopened aluminium pouches).

2. Click **Load** in the **CD Data** section. The **Load** (CD) dialog opens.

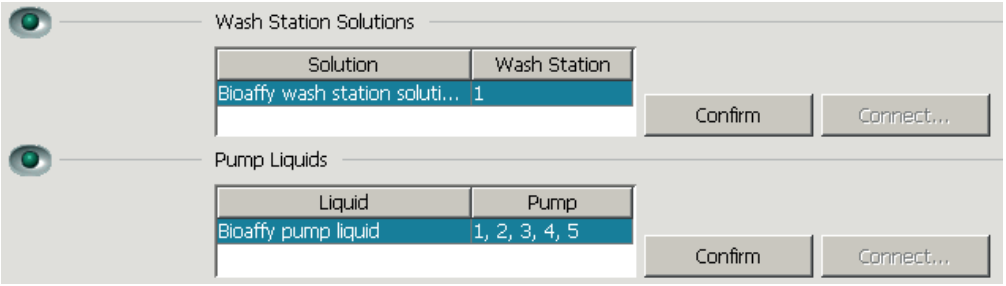

Load
Load
Close
1. Insert CD into instrument.
2. Press Load or use CD-button in instrument to load CD.
1 CD is required, 0 are loaded.
Method requires Gyrolab Bioaffy 200.
CD id:

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
3.	Open the aluminium pouch and place the CD in loading position, refer to Chapter A2.2.1. Touch only the outer edge of the CDs. Do not touch the surface of the CD. Start the Run within 15 minutes after the CD has been taken out from its pouch. Protect the CD from extended illumination from indoor lighting or sunlight since this may affect data quality. Click **Load** in **Load** dialog or press **CD** button on the instrument (refer to Chapter A2.2.1). The system identifies the CD and the CD identity appears in the list on screen. Repeat for all CDs. ***NOTE:*** ***The number of CDs required and the number that have been loaded are displayed at the bottom of the screen. The LED will not be lit until all required CDs have been loaded.***

B5.1.2.1 Confirm Wash Station Solutions and Pump Liquid

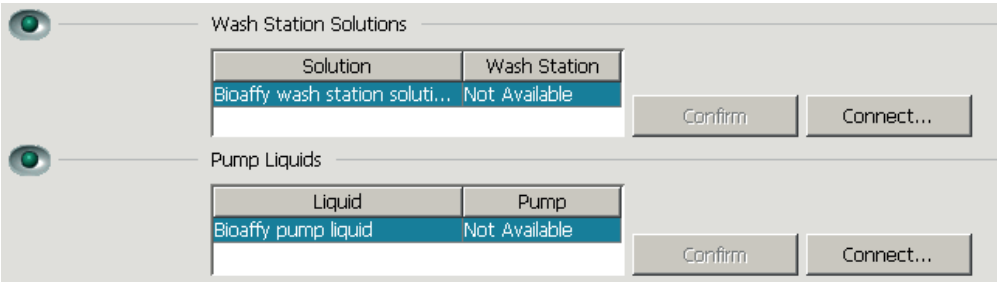
If solutions and liquids are available:



Step	Action
1.	Make sure tubings for wash station solution and pump liquid are connected and system is primed according to Chapter B2.4.
2.	Under **Wash Station Solutions**: Highlight the Wash Station Solution and click **Confirm**.
3.	Under **Pump Liquid** section: Highlight the Bioaffy Pump Liquid and click **Confirm**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

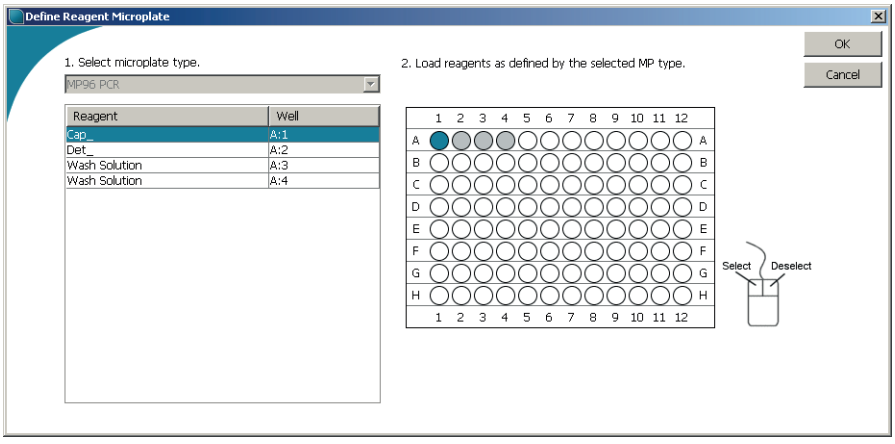
If solutions and liquids are not available:



Step	Action
1.	Make sure tubings for wash station solution and pump liquid are connected and system is primed according to Chapter B2.4.
2.	Under **Wash Station Solutions** • Click **Connect**. Click **OK** in the **Connect Wash Station** dialog that opens.
3.	Under **Pump Liquids** • Click **Connect**. • Click **Confirm** in the **Pump Liquid** dialog that opens.

B5.1.2.2 Load reagent microplate

Step	Action
1.	Click **Load** in the **Reagents** section. The **Define Reagent Microplate** dialog box is displayed.

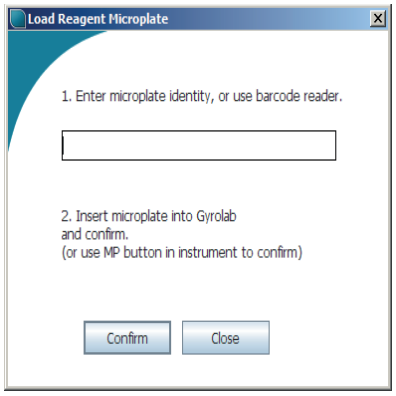


2.	Verify that the reagents are placed correctly in the microplate according to the Gyrolab Control Loading list.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

3. Click **OK**. The load reagent microplate dialog appears:


Load Reagent Microplate
1. Enter microplate identity, or use barcode reader.
2. Insert microplate into Gyrolab
and confirm.
(or use MP button in instrument to confirm)
Confirm
Close

- Either scan the barcode ID, or click **Enter ID Manually** and enter microplate ID as stated in the Loading List.*
- Insert sample microplate in loading position (Chapter A2.2.1).
- Click **Confirm**. The microplate ID will appear in the list on screen.

4. Repeat for each reagent microplate until all reagent microplates are loaded.

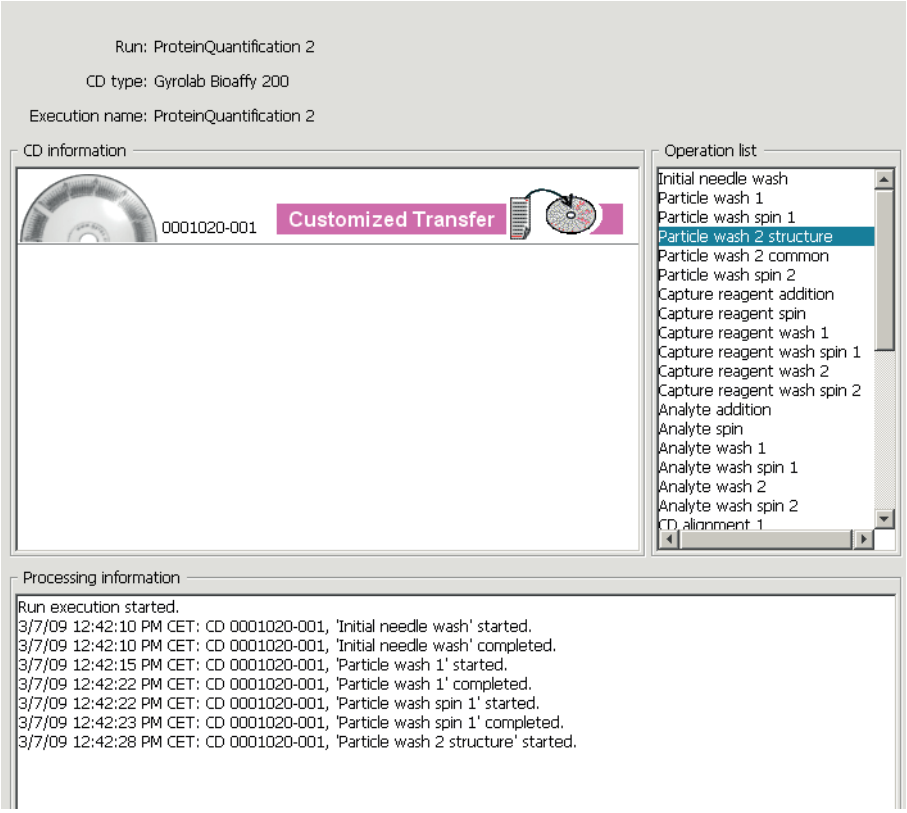
* Ensure the BCR is configured so that **Enter** or **Carriage Return** is not added when scanning the identity of a MP

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B5.1.3 Start Run

When loading is completed, as confirmed by all green LEDs being lit on screen, the Run can be started.

Step	Action
1.	Close the instrument hatch.
2.	Click **Start**. An event log is displayed where all steps of the Run are registered along with event time.


Run: ProteinQuantification 2
CD type: Gyrolab Bioaffy 200
Execution name: ProteinQuantification 2
CD information
0001020-001
Customized Transfer
Operation list
Initial needle wash
Particle wash 1
Particle wash spin 1
Particle wash 2 structure
Particle wash 2 common
Particle wash spin 2
Capture reagent addition
Capture reagent spin
Capture reagent wash 1
Capture reagent wash spin 1
Capture reagent wash 2
Capture reagent wash spin 2
Analyte addition
Analyte spin
Analyte wash 1
Analyte wash spin 1
Analyte wash 2
Analyte wash spin 2
CD alignment 1
Processing information
Run execution started.
3/7/09 12:42:10 PM CET: CD 0001020-001, 'Initial needle wash' started.
3/7/09 12:42:10 PM CET: CD 0001020-001, 'Initial needle wash' completed.
3/7/09 12:42:15 PM CET: CD 0001020-001, 'Particle wash 1' started.
3/7/09 12:42:22 PM CET: CD 0001020-001, 'Particle wash 1' completed.
3/7/09 12:42:22 PM CET: CD 0001020-001, 'Particle wash spin 1' started.
3/7/09 12:42:23 PM CET: CD 0001020-001, 'Particle wash spin 1' completed.
3/7/09 12:42:28 PM CET: CD 0001020-001, 'Particle wash 2 structure' started.

3. It is possible to pause or abort an ongoing run:
   - To stop an ongoing Run, click **Abort**. The Run is immediately terminated and cannot be resumed. Remove all CDs and microplates as described in Chapter B6.1.1. Do not use results or CDs from aborted Runs as there is a risk that data or the CDs may have been corrupted.
   - The pause an ongoing run, click **Pause**. To resume the Run, click **Resume**.
4. The system stops automatically when the run is completed. Click **Finish**.

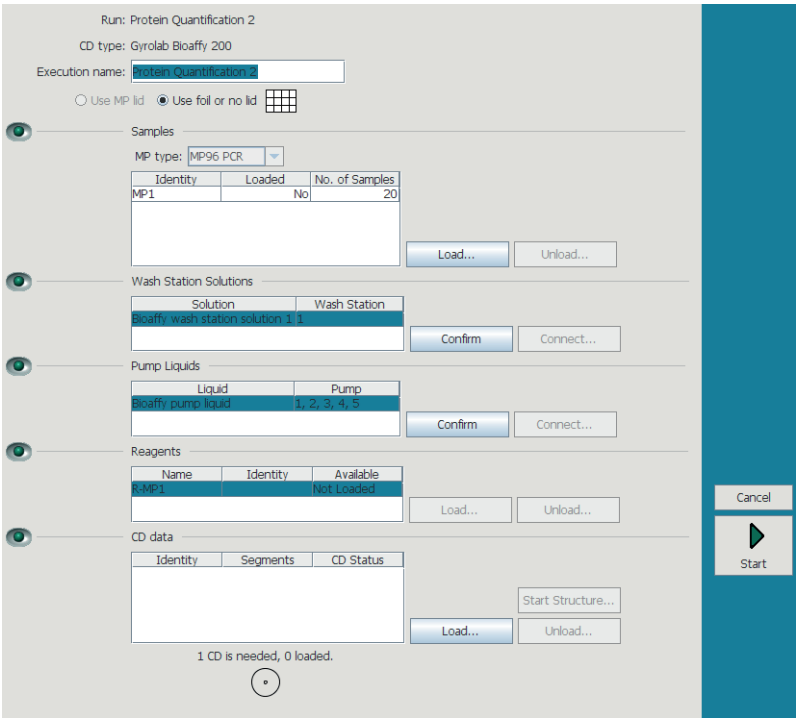
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B5.2 Instructions for Gyrolab xPlore

B5.2.1 Load Gyrolab instrument

Before starting the instrument loading procedure, ensure that run preparations and sample and reagent preparations have been performed according to Chapter B3 and Chapter B4.

Step	Action
1.	The following screen should be shown after the clicking **OK** in the last step in Chapter B3.2.4.

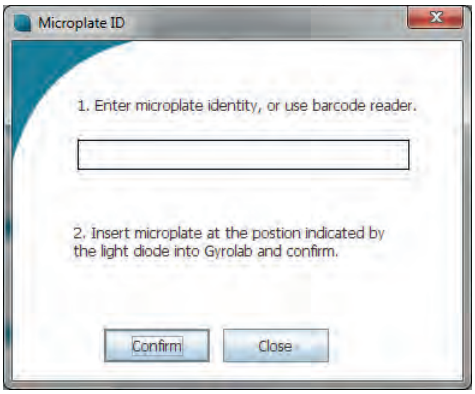


The screen is a check list for the loading steps. Upon completion of each step, the corresponding green LED on the left panel is lit. A Run cannot be started until all LEDs are lit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B5.2.1.1 Load sample microplates

Step	Action
1.	Click **Load** in the **Samples** section. The **Microplate ID** dialog appears:


Microplate ID
1. Enter microplate identity, or use barcode reader.
2. Insert microplate at the postion indicated by the light diode into Gyrolab and confirm.
Confirm
Close

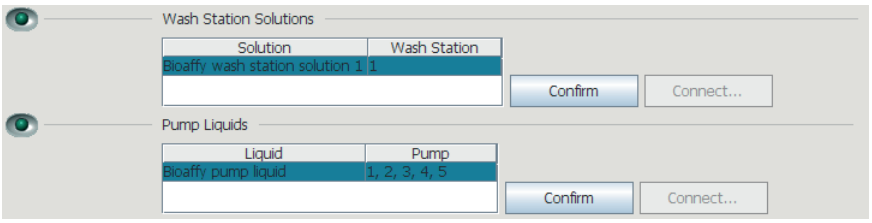
- Either scan the barcode ID, or click **Enter ID Manually** and enter microplate ID as stated in the Loading List.*
- Insert sample microplate in loading position indicated by the light LED (Chapter A2.2.2).
- Click **Confirm**. The microplate ID will appear in the list on screen.

2.	Repeat for each sample microplate until all sample microplates are loaded.

* Ensure the BCR is configured so that **Enter** or **Carriage Return** is not added when scanning the identity of a MP

B5.2.1.2 Confirm Wash Station Solutions and Pump Liquid

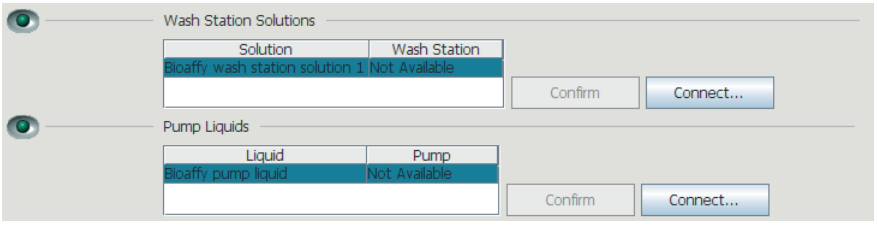
If solutions and liquids are available:



Step	Action
1.	Make sure tubings for wash station solution and pump liquid are connected and system is primed according to Chapter B2.4.
2.	Under **Wash Station Solutions**: Highlight the Wash Station Solution and click **Confirm**.
3.	Under **Pump Liquid** section: Highlight the Bioaffy Pump Liquid and click **Confirm** (Chapter A2.2.2).

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

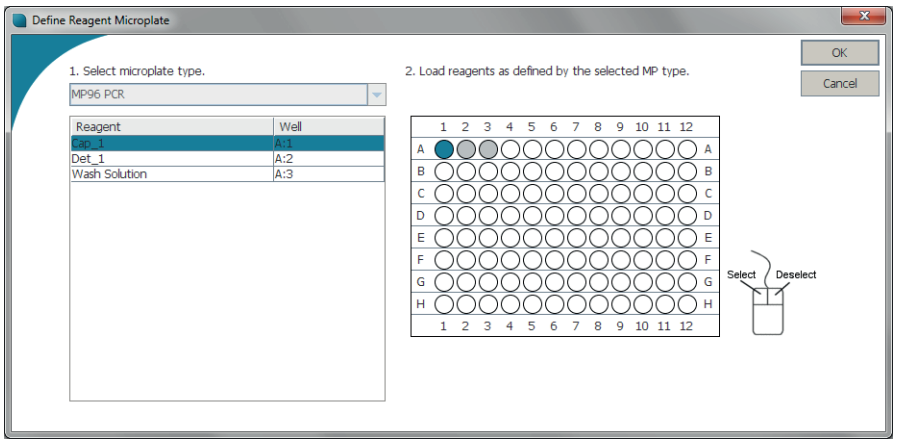
If solutions and liquids are not available:



Step	Action
1.	Make sure tubings for wash station solution and pump liquid are connected and system is primed according to Chapter B2.4.
2.	Under **Wash Station Solutions** • Click **Connect**. Click **OK** in the **Connect Wash Station** dialog that opens.
3.	Under **Pump Liquids** • Click **Connect**. • Click **Confirm** in the **Pump Liquid** dialog that opens.

B5.2.1.3 Load reagent microplate

Step	Action
1.	Click **Load** in the **Reagents** section. The **Define Reagent Microplate** dialog box is displayed.

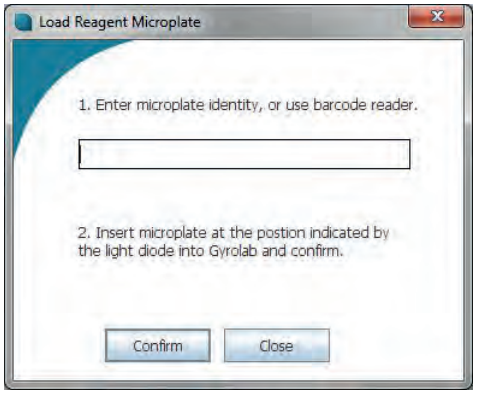


2.	Verify that the reagents are placed correctly in the microplate according to the Gyrolab Control Loading list.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

3. Click **OK**. The load reagent microplate dialog appears:


Load Reagent Microplate
1. Enter microplate identity, or use barcode reader.
2. Insert microplate at the postion indicated by the light diode into Gyrolab and confirm.
Confirm
Close

- Either scan the barcode ID, or click **Enter ID Manually** and enter microplate ID as stated in the Loading List.*
- Insert sample microplate in loading position indicated by the light LED (Chapter A2.2.2).
- Click **Confirm**. The microplate ID will appear in the list on screen.

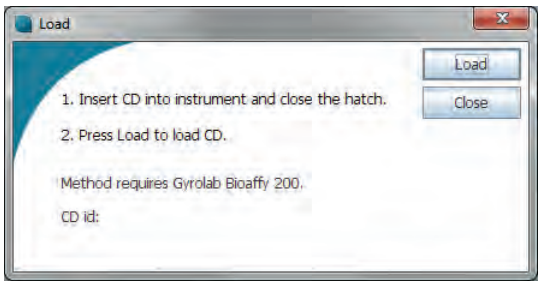
4. Repeat for each reagent microplate until all reagent microplates are loaded.

* Ensure the BCR is configured so that **Enter** or **Carriage Return** is not added when scanning the identity of a MP

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B5.2.2 Load CDs

Step	Action
1.	Put CDs in room temperature for 30 minutes (in the unopened aluminium pouches).
2.	Click **Load** in the **CD Data** section. The **Load** (CD) dialog opens.



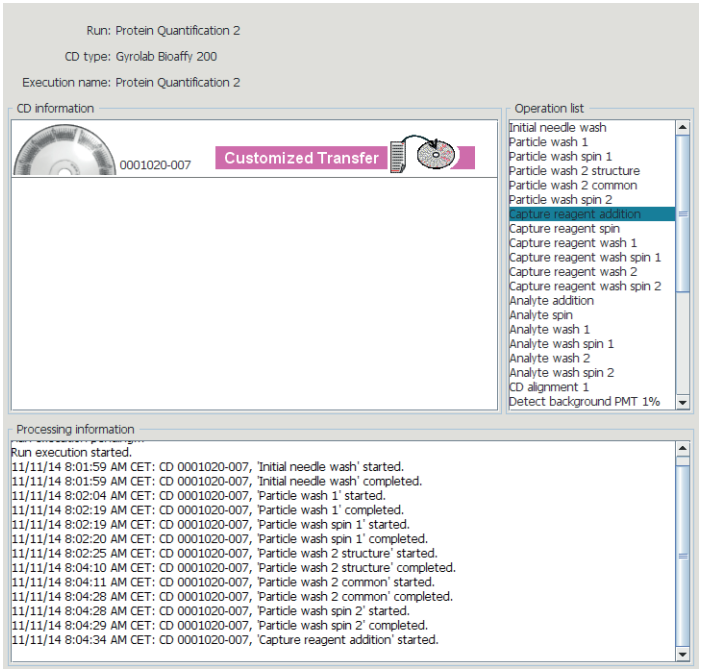
3.	Open the aluminium pouch and place the CD in loading position, refer to Chapter A2.2.2. Touch only the outer edge of the CDs. Do not touch the surface of the CD. Start the Run within 15 minutes after the CD has been taken out from its pouch. Protect the CD from extended illumination from indoor lighting or sunlight since this may affect data quality. Close the hatch and click **Load** in **Load** dialog. The system identifies the CD and the CD identity appears in the list on screen.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B5.2.3 Start Run

When loading is completed, as confirmed by all green LEDs being lit on screen, the Run can be started.

Step	Action
1.	Close the instrument hatch.
2.	Click **Start**. An event log is displayed where all steps of the Run are registered along with event time.


Run: Protein Quantification 2
CD type: Gyrolab Bioaffy 200
Execution name: Protein Quantification 2
CD information
0001020-007
Customized Transfer
Operation list
Initial needle wash
Particle wash 1
Particle wash spin 1
Particle wash 2 structure
Particle wash 2 common
Particle wash spin 2
Capture reagent addition
Capture reagent spin
Capture reagent wash 1
Capture reagent wash spin 1
Capture reagent wash 2
Capture reagent wash spin 2
Analyte addition
Analyte spin
Analyte wash 1
Analyte wash spin 1
Analyte wash 2
Analyte wash spin 2
CD alignment 1
Detect background PMT 1%
Processing information
Run execution started.
11/11/14 8:01:59 AM CET: CD 0001020-007, 'Initial needle wash' started.
11/11/14 8:01:59 AM CET: CD 0001020-007, 'Initial needle wash' completed.
11/11/14 8:02:04 AM CET: CD 0001020-007, 'Particle wash 1' started.
11/11/14 8:02:19 AM CET: CD 0001020-007, 'Particle wash 1' completed.
11/11/14 8:02:19 AM CET: CD 0001020-007, 'Particle wash spin 1' started.
11/11/14 8:02:20 AM CET: CD 0001020-007, 'Particle wash spin 1' completed.
11/11/14 8:02:25 AM CET: CD 0001020-007, 'Particle wash 2 structure' started.
11/11/14 8:04:10 AM CET: CD 0001020-007, 'Particle wash 2 structure' completed.
11/11/14 8:04:11 AM CET: CD 0001020-007, 'Particle wash 2 common' started.
11/11/14 8:04:28 AM CET: CD 0001020-007, 'Particle wash 2 common' completed.
11/11/14 8:04:28 AM CET: CD 0001020-007, 'Particle wash spin 2' started.
11/11/14 8:04:29 AM CET: CD 0001020-007, 'Particle wash spin 2' completed.
11/11/14 8:04:34 AM CET: CD 0001020-007, 'Capture reagent addition' started.

3. It is possible to pause or abort an ongoing run:
   - To stop an ongoing Run, click **Abort**. The Run is immediately terminated and cannot be resumed. Remove all CDs and microplates as described in Chapter B6.2.1. Do not use results or CDs from aborted Runs as there is a risk that data or the CDs may have been corrupted.
   - The pause an ongoing run, click **Pause**. To resume the Run, click **Resume**.
4. The system stops automatically when the run is completed. Click **Finish**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B6 After Run procedures and result export

NOTE: There are two separate instructions, one for Gyrolab xP and one for Gyrolab xPlore.

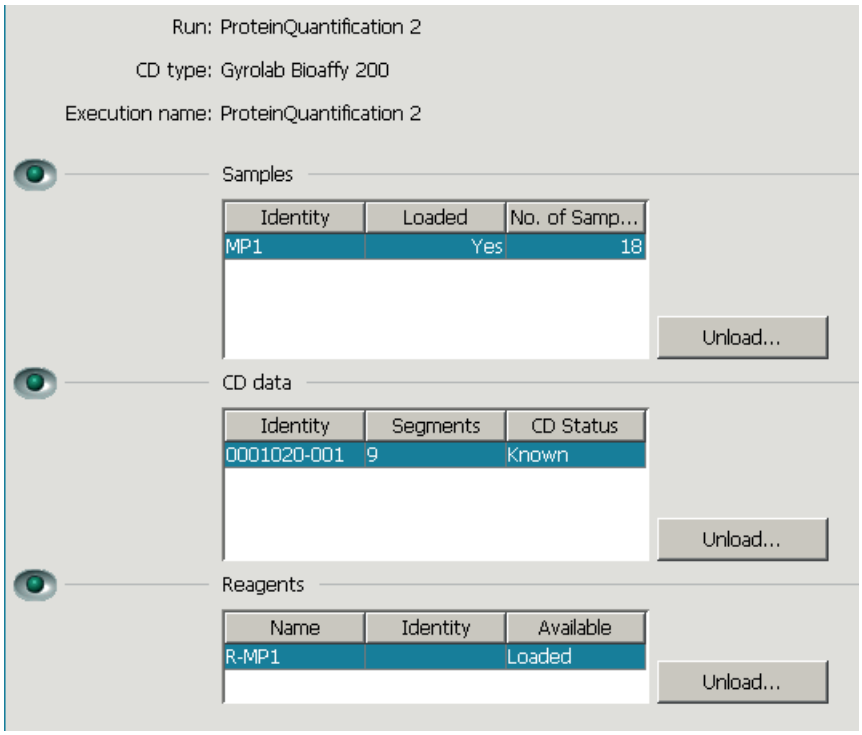
B6.1 Instructions for Gyrolab xP

B6.1.1 Finish Run

When the Run is completed microplates and CDs must be unloaded from the instrument.

Unloading is carried out in the same way as the system is loaded, that is by following the instructions on the screen. After each step has been completed, a green LED is lit on the left side of each section.

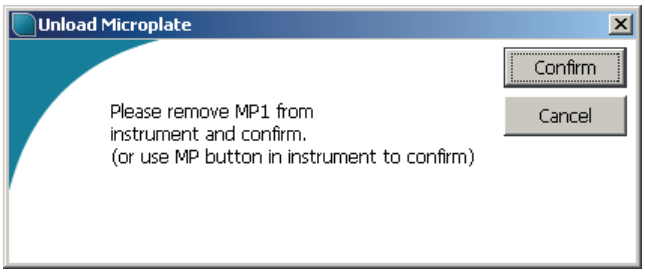
Step	Action
1.	The system stops automatically when the run is completed. Click **Finish**. The **Execute Run** screen, a checklist for unloading, appears:



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

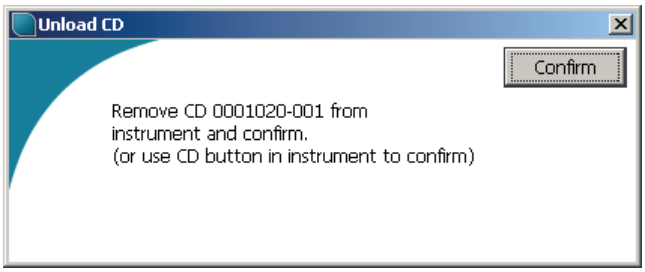
Step	Action

2. In **Samples** section, click **Unload**. The **Unload Microplate** dialog opens.



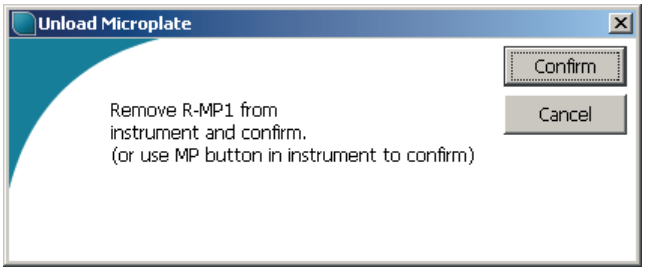
- Remove plate.
- Click **Confirm**.
- Repeat for all microplates.

3. In **CD Data** section, click **Unload**. The **Unload CD** dialog opens.



- Remove CD.
- Click **Confirm**.
- Repeat for all CDs.

4. In **Reagents** section, click **Unload**. The **Unload Microplate** dialog opens.



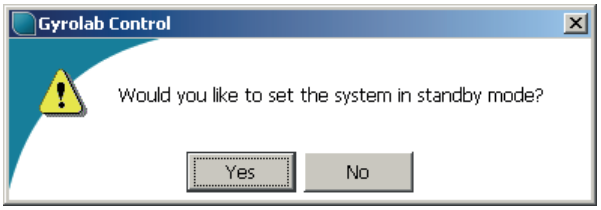
- Remove plate.
- Click **Confirm**.
- Repeat for all Reagent Microplates.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
5.	Click **Finish**.

NOTE: ***Finish cannot be activated until all LEDs are lit in the screen to indicate that unloading is complete.***

The **Standby** dialog opens.



- If another Run is scheduled later during the day, click **No** and start the new run.
- If it is the last Run of the day, click **Yes**. The **Ensure enough standby solution is available** dialog opens. Connect tubings for Standby solutions and click **OK**. Standby procedures will start.

  Standby procedures means priming Syringe Pumps and Wash Stations with **Standby Solution**. It is recommended to put system in Standby mode at least three times a week. For more information, refer to Gyrolab Instrument Guide for Gyrolab xP.

B6.1.2 How to turn Gyrolab off

Before turning the instrument off for a longer period of time it is recommended to put the instrument in Standby mode, see Gyrolab Instrument Guide for Gyrolab xP.

Step	Action
1.	Right-click on the Gyrolab server icon and select **Instrument/Go to Offline state** (This is required before the instrument controller computer can be shut down).
2.	Press **OK** to Acknowledge Instrument Offline State.
3.	After about 10 seconds, right-click on the Gyrolab server icon and select **Instrument/Shutdown** (This will power off the instrument controller computer in a controlled way).
4.	Press OK to shut down the instrument.
5.	After about 30 seconds, a dialog box will appear:

- Press **OK** and wait at least 20 seconds before turning off the instrument via the power switch. In addition, for instruments below Serial Number GW10159, power off the white instrument controller.
- Right click on the Server icon (the Instrument line will no longer be present) and click on **Shut down Gyrolab Server.** Click on the **Yes** button in the resulting pop-up box.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B6.1.3 Generated Gyrolab Control files

There are four types of files generated by Gyrolab Control. Files are available in the Gyrolab database and accessible through Gyrolab Database Explorer.

Copies of files may be available in other locations as set during run preparations. The locations are displayed in the log panel after a Run.

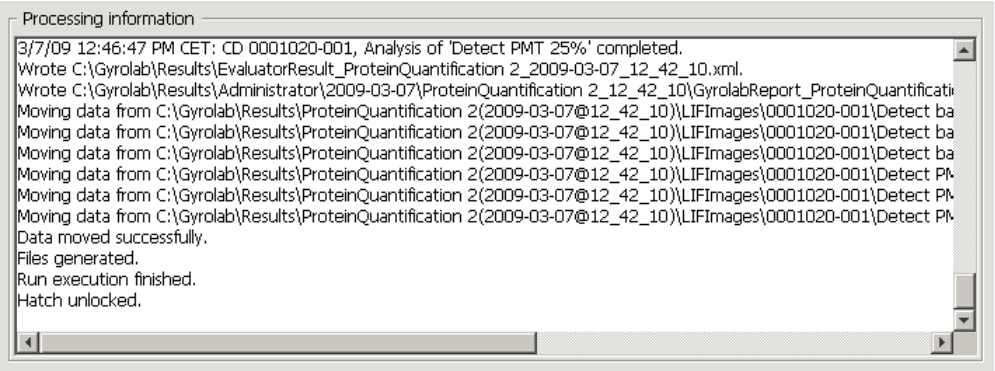

Processing information
3/7/09 12:46:47 PM CET: CD 0001020-001, Analysis of 'Detect PMT 25%' completed.
Wrote C:\Gyrolab\Results\EvaluatorResult_ProteinQuantification 2_2009-03-07_12_42_10.xml.
Wrote C:\Gyrolab\Results\Administrator\2009-03-07\ProteinQuantification 2_12_42_10\GyrolabReport_ProteinQuantificati
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect ba
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect ba
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect ba
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect PM
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect PM
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect PM
Data moved successfully.
Files generated.
Run execution finished.
Hatch unlocked.

Figure 1: Run log panel showing location of generated files.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B6.2 Instructions for Gyrolab xPlore

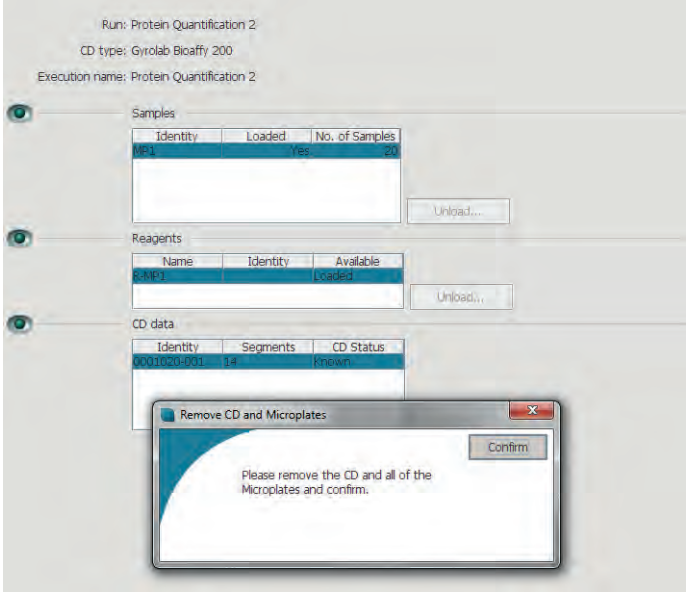
B6.2.1 Finish Run

When the Run is completed microplates and CD must be unloaded from the instrument.

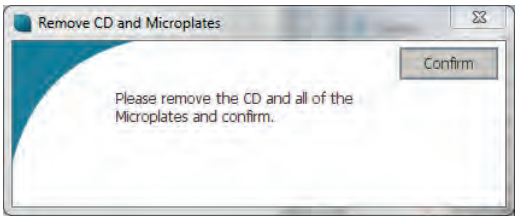
Unloading is carried out in the same way as the system is loaded, that is by following the instructions on the screen. After each step has been completed, a green LED is lit on the left side of each section.

Step	Action

1. The system stops automatically when the run is completed. Click **Finish**. The **Execute Run** screen, a checklist for unloading, appears with a dialog:



2. When the **Remove CD and Microplates** dialog opens:



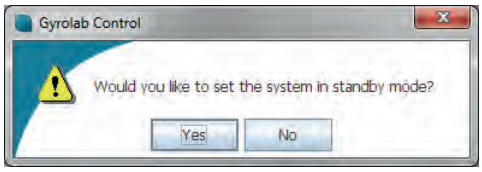
- Remove all of the Microplates.
- Remove CD.
- Click **Confirm**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
3.	Click **Finish**.

NOTE: ***Finish cannot be activated until all LEDs are lit in the screen to indicate that unloading is complete.***

The **Standby** dialog opens.



- If another Run is scheduled later during the day, click **No** and start the new run.
- If it is the last Run of the day, click **Yes**. The **Ensure enough standby solution is available** dialog opens. Connect tubings for Standby solutions and click **OK**. Standby procedures will start.

  Standby procedures means priming Syringe Pumps and Wash Stations with **Standby Solution**. It is recommended to put system in Standby mode at least three times a week. For more information, refer to Gyrolab Instrument Guide for Gyrolab xPlore.

B6.2.2 How to turn Gyrolab off

Before turning the instrument off for a longer period of time it is recommended to put the instrument in Standby mode, see Gyrolab Instrument Guide for Gyrolab xPlore.

B6.2.2.1 Shut down the Instrument

Step	Action
1.	Right-click on the Gyrolab server icon and select **Instrument/Shutdown** (This will unload the instrument software and power off the instrument).
2.	Press the power button on the Instrument for more than 5 seconds (Chapter A2.2.2).

NOTE: ***The instrument will shutdown even if a run is in progress***

After the button has been pressed down for 5 seconds the following will happen:

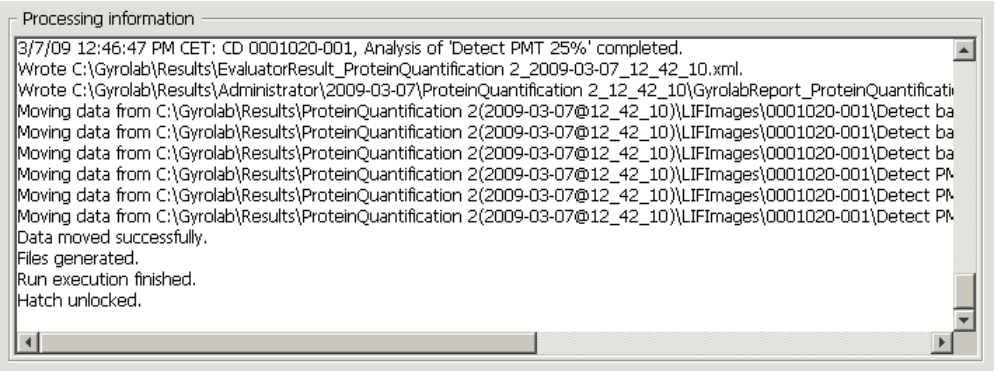
- Instrument software is unloaded
- Power is cut

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

B6.2.3 Generated Gyrolab Control files

There are four types of files generated by Gyrolab Control. Files are available in the Gyrolab database and accessible through Gyrolab Database Explorer.

Copies of files may be available in other locations as set during run preparations. The locations are displayed in the log panel after a Run.


Processing information
3/7/09 12:46:47 PM CET: CD 0001020-001, Analysis of 'Detect PMT 25%' completed.
Wrote C:\Gyrolab\Results\EvaluatorResult_ProteinQuantification 2_2009-03-07_12_42_10.xml.
Wrote C:\Gyrolab\Results\Administrator\2009-03-07\ProteinQuantification 2_12_42_10\GyrolabReport_ProteinQuantificati
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect ba
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect ba
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect ba
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect PM
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect PM
Moving data from C:\Gyrolab\Results\ProteinQuantification 2(2009-03-07@12_42_10)\LIFImages\0001020-001\Detect PM
Data moved successfully.
Files generated.
Run execution finished.
Hatch unlocked.

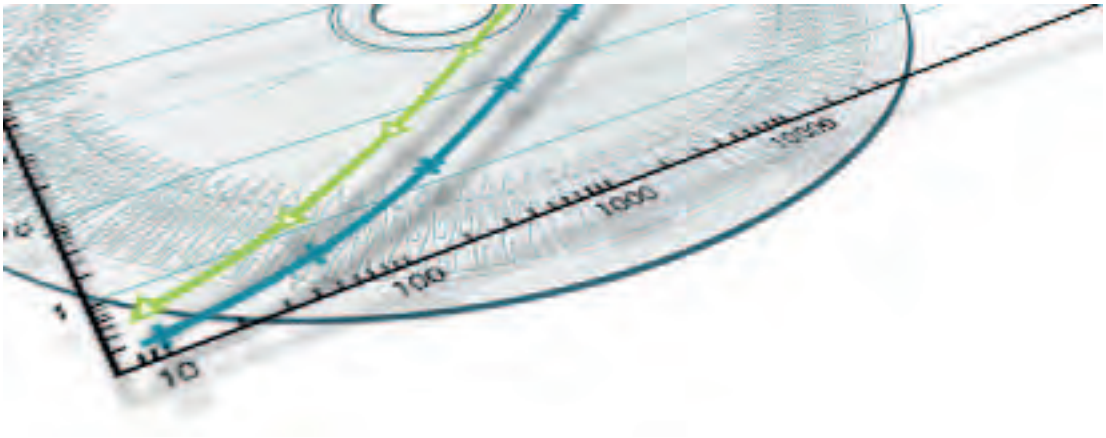
Run log panel showing location of generated files.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

GYROLAB USER GUIDE

C Data analysis



Contents

C1 Introduction to data evaluation C-5

C1.1 Gyrolab Evaluator introduction C-5

C1.2 Gyrolab Evaluator main features C-5

C1.2.1 Data analysis C-5

C1.2.2 Analysis settings C-5

C1.2.3 Storage of analyses C-6

C1.2.4 Traceability of analyses C-6

C1.2.5 Export of reports C-6

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C2 Log in, main menu functions and analysis administration C-7

C2.1 Start and log in C-7

C2.2 Main menu functions C-9

C2.2.1 New Analysis menu C-9

C2.2.2 Open Project menu C-10

C2.2.3 Manage menu C-10

C2.2.4 Recent Runs menu C-16

C2.3 Gyrolab Evaluator Audit trail C-16

C2.4 Close Gyrolab Evaluator C-16

C3 Manage analysis projects C-17

C3.1 Project view C-17

C3.2 Add and remove run in Project C-19

C3.3 Add, remove and export analyses in a Project C-19

C3.4 Open a Project C-20

C3.5 Save a Project C-20

C3.6 Close a Project C-21

C3.7 Approve/Unapprove a Project C-21

C3.8 Set analysis settings for a Project C-22

C3.9 Manage Folder structure C-26

C3.10 Audit trail for Projects C-26

C3.11 Reports and report data export C-27

C3.11.1 Report content C-27

C3.11.2 View, print and export report data C-27

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C4 Analyze data C-29

C4.1 Quantification module C-29

C4.2 Data Comparison module C-34

C4.3 Result data table descriptions C-38

C4.4 Analysis settings C-41

C4.4.1 Curve fit models C-43

C5 Gyrolab Evaluator installation on office computer. . . C-45

C5.1 Gyrolab Evaluator installation package C-45

C5.2 Computer requirements C-45

C5.3 User level requirements C-45

C5.4 Installation C-46

C5.5 Database configuration C-50

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C1 Introduction to data evaluation

This chapter gives an introduction to, and describes structure and functionalities available within Gyrolab Evaluator.

C1.1 Gyrolab Evaluator introduction

Gyros provides software to facilitate data evaluation of Runs performed on the Gyrolab instrument.

- **Gyrolab Evaluator** is part of the base software package installed on all Gyrolab systems. It is designed analyze data from Gyrolab Runs. Several evaluation functions and setting options are available to achieve optimal quantification results. For an introduction to Gyrolab Evaluator, refer to Chapter C1 and for instructions on how to use Gyrolab Evaluator, refer to Chapter C4.

Available Add-ons and plug-ins:

- **Gyrolab Viewer** is an add-on software module to Gyrolab Evaluator used to study the binding profiles in Bioaffy CD columns produced during data evaluation. This can be useful during assay optimization to help identify suitable reagents, during trouble shooting to investigate outliers and for quality control purposes. For instructions on how to use Gyrolab Viewer, refer to Chapter D1.
- **Serial Dilution Analysis** is a plug-in to Gyrolab Evaluator used for automatic evaluation of spike recovery to verify the sample analysis accuracy using dilution series of spiked and unspiked unknown samples. For instructions on how to use Gyrolab Viewer, refer to Chapter D5.

C1.2 Gyrolab Evaluator main features

C1.2.1 Data analysis

Using the **Quantification** module, analyses of selected Runs using certain analysis settings are performed. Different analysis settings can be tested to find optimal curve fits. Samples are quantified using the selected Analysis settings. Subsets of Run results are selected for inclusion in Reports and the resulting analysis report is displayed in the Project view under **Analyses:Quantification** (refer to Chapter C4.1).

Different analyses are compared using the **Data Comparison** module (Chapter C4.2). For example is it possible to compare sample data and standard curves from different experiments in the same Run or from different Runs. This can for example be used when comparing different assay development Runs, when comparing routine analyses performed at different occasions or for quality tests. Data to be compared must be analyzed in the same Project.

C1.2.2 Analysis settings

There are several settings available for data analysis. Examples of analysis settings for the Quantification module are curve fit models and acceptance criteria. Analysis settings can be set for an entire **Project** (option to lock settings), refer to Chapter C3.8, or for a specific analysis, refer to Chapter C4.1.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C1.2.3 Storage of analyses

In order to store analyses of Run results in a traceable way, compliant to GxP requirements, the following features are used.

- Project: Run results from one or more Runs are added to analysis entities named Projects. Within a Project, selected Run results are analyzed using one or several analysis modules. The resulting **Analyses** are included in the Project. Analysis setting may be locked for a Project. All analyses are logged in the **Audit trail**. If the Project is set to **Approved** status it can be opened and viewed but no additional analyses can be made.
- Folder structure: In order to organize Projects, a folder structure is available.
- Run result files, Analyses, Projects and Structure folders are stored in a specific Gyrolab database connected to the Gyrolab Evaluator.

C1.2.4 Traceability of analyses

- To ensure data integrity and traceability to comply with GxP requirements, all data modifications are recorded in an **Audit Trail** (Chapter C2.3 and Chapter C3.10).
- To further increase traceability, it is possible to require users to enter change descriptions for Analyses and Projects.

C1.2.5 Export of reports

Analysis reports and Audit trail reports can be exported in different formats, refer to Chapter C2.3 and Chapter C3.11.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C2 Log in, main menu functions and analysis administration

This chapter describes log in procedure and available functions in the main menu of Gyrolab Evaluator.

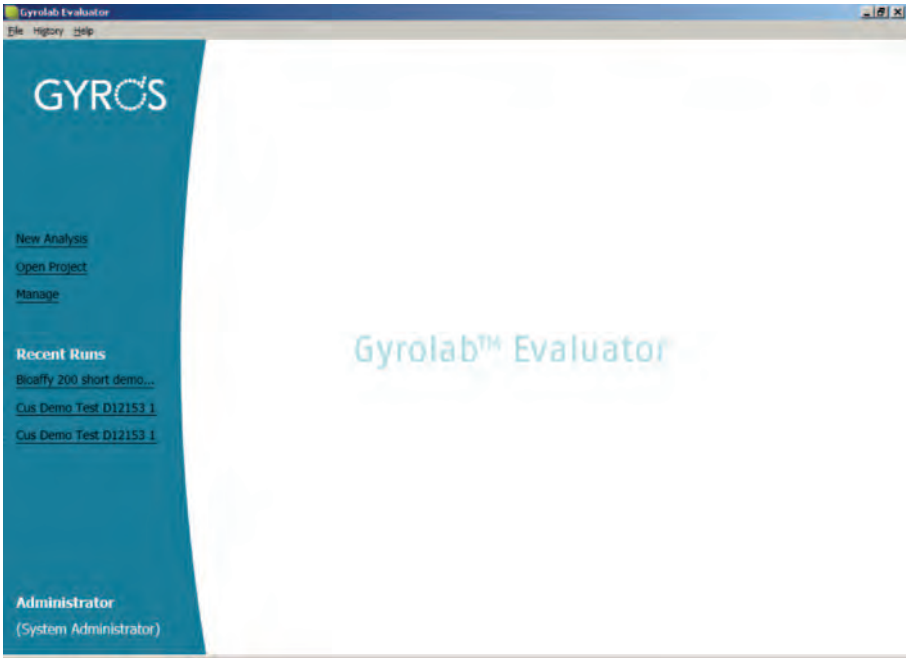
For instructions on how to install Gyrolab Evaluator on a office computer, refer to Chapter C5.

C2.1 Start and log in

Step	Action
1.	Start Gyrolab Evaluator: Select **Start:All Programs:Gyros:Gyrolab Evaluator**.
2.	Enter user name and password in the **Login** dialog box and click **OK**. The user name and password is the same for all Gyrolab software. For further information on user and password administration, refer to Chapter F2.2.6. Password must be changed if requested by the software, for example when a new user logs in or if 90 days have passed since last password change. Password may also be changed when desired by the user. To change password: • Mark the check-box **Change Password.** • Enter current password in **Password** field, new password in **New Password** field and confirm new password in **Confirm Password** field. • Click **OK**. ***NOTE: User name and password are case sensitive.*** ***NOTE: The software will request the user to log in anew when the system has been inactive for 31 minutes.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
3.	Gyrolab Evaluator Start view opens.



The following options are available:

- Click **New Analysis** to add Run(s) to a new Project, perform analysis and then save or discard the new Project, refer to Chapter C2.2.
- Click **Open Project** to open an existing Project to view or add/remove Runs and analysis in the Project, refer to Chapter C2.2.2.
- Click **Manage** to create a new Project, edit analysis setting for a Project, manage the Folder structure or perform searches within Projects, refer to Chapter C2.2.3. Access to the Manage menu requires System Administrator or Project Manager user level privileges (refer to Chapter F2.2.6)
- Click on desired Run under **Recent Runs** to add this run to a new Project, refer to Chapter C2.2.4.

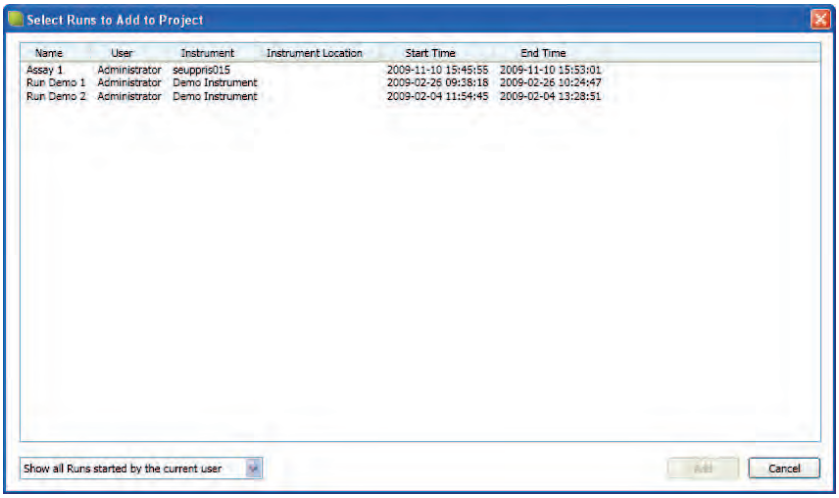
In the lower left corner current user and its user level is shown. Some actions are restricted to certain user levels. For information of user levels, refer to Chapter F2.2.6.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C2.2 Main menu functions

C2.2.1 New Analysis menu

Step	Action
1.	Click **New Analysis** in Gyrolab Evaluator start view.
2.	A dialog opens. Select one or more Runs to be analyzed and click **Add**.


Select Runs to Add to Project
Name
User
Instrument
Instrument Location
Start Time
End Time
Assay 1 Administrator seuppris015 2009-11-10 15:45:55 2009-11-10 15:53:01
Run Demo 1 Administrator Demo Instrument 2009-02-26 09:28:18 2009-02-26 10:24:47
Run Demo 2 Administrator Demo Instrument 2009-02-04 11:54:45 2009-02-04 13:28:51
Show all Runs started by the current user
Add
Cancel

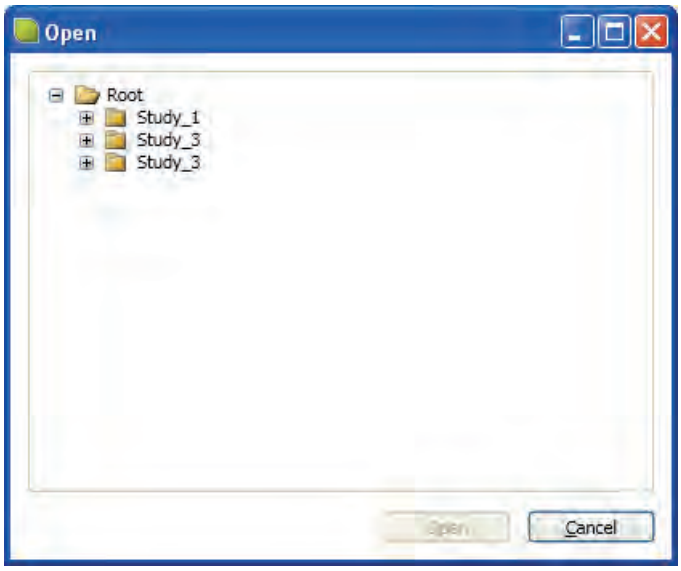
- Unselect a Run by clicking on the name again.
- Use the list in the lower left corner to view different subsets of Runs or all available Runs.

3.	Gyrolab Evaluator Project view opens. • For more information on the Project view and how to manage and save the new Project, refer to Chapter C3. • To perform data analysis on a Run, refer to Chapter C4.1 and Chapter C4.2 • To discard the project, click **File:Close** or the or click Close button to close the Project.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C2.2.2 Open Project menu

Step	Action
1.	Click **Open Project** in Gyrolab Evaluator start view.
2.	The **Open** widow is displayed. In the Folder structure, browse to find the desired Project.



Select Project and click **Open**.

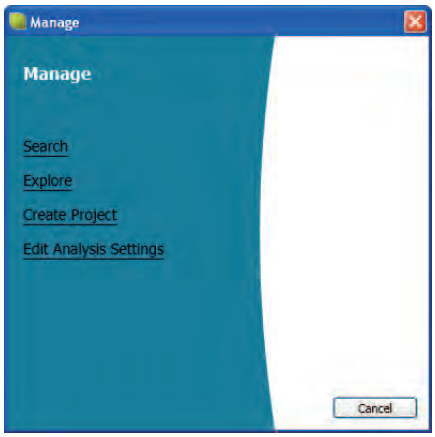
3.	Gyrolab Evaluator Project view opens.

- To manage and save the Project, refer to Chapter C3.
- To perform data analysis on a Run, refer to Chapter C4.1 and Chapter C4.2.

C2.2.3 Manage menu

The **Manage** menu holds functionality to administrate Projects.

- To search for folders Project, Runs and Analyses, refer to Chapter C2.2.3.1
- To explore and administrate Folder structure, refer to Chapter C2.2.3.2
- To create a new Project, refer to Chapter C2.2.3.3
- To edit analysis settings for a Project, refer to Chapter C2.2.3.4



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

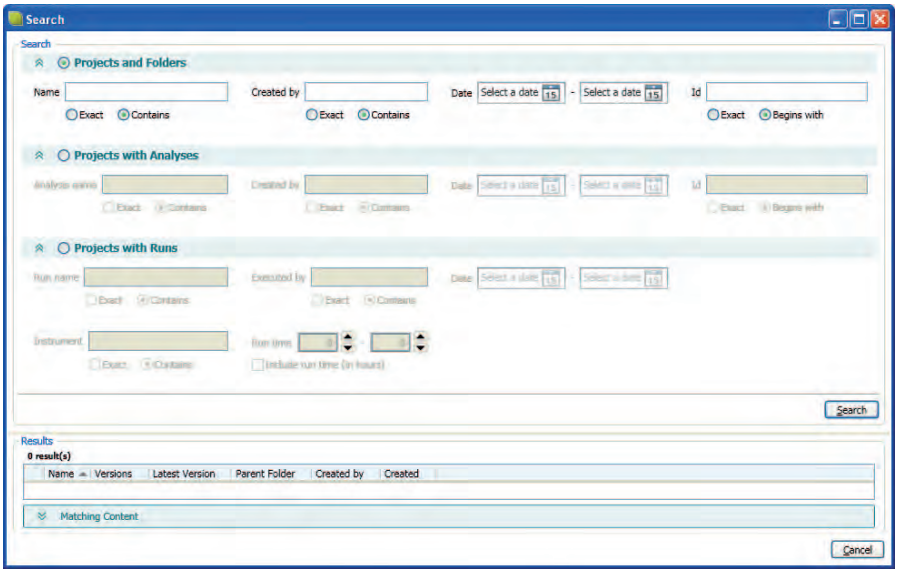
C2.2.3.1 Search for Folders, Projects, Runs and Analyses

Step	Action

1. Click **Manage** in Gyrolab Evaluator start view, and click **Search** in the **Manage** window.

2. In the **Search** section, set search criteria for one of the following items:

   - Projects and Folders
   - Projects with Analysis
   - Projects with Runs



3. For Projects and Analyses it is possible include identity number in search criteria. The identity number is a unique identifier for the Project or Analysis.

   Project identity number is found on Projects that have been printed or been saved to .xps format.

   Analysis identity number is found at the bottom of Analysis reports.

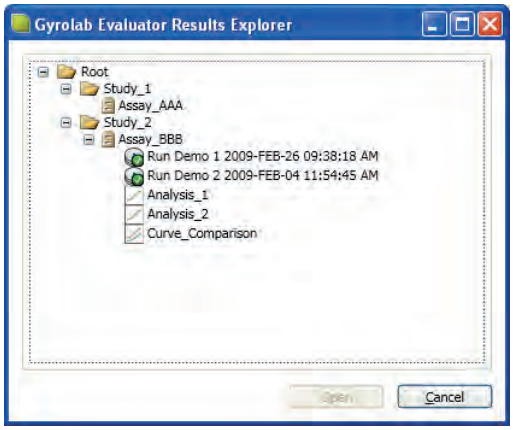
4. Click **Search.**

5. Results are displayed in the **Results** section. Sort by specific column by clicking on column title.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

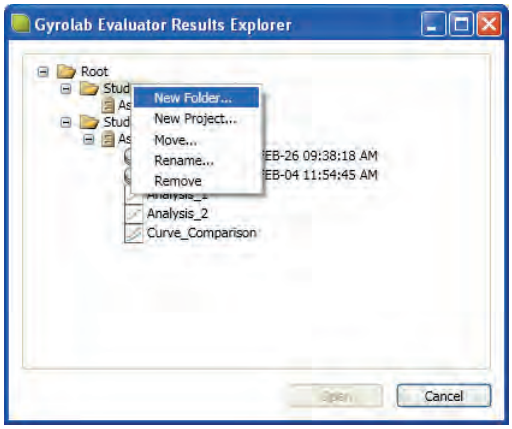
C2.2.3.2 Explore folder structure

Step	Action
1.	Click **Manage** in Gyrolab Evaluator start view, and click **Explore** in the **Manage** window.
2.	A window opens where it is possible to browse Folders, Projects, Runs and Analyses (analysis icon differs depending on analysis type) It is also possible to create new Folders and Projects and to move, rename and remove Folders and Projects, refer to step 3 – step 5.

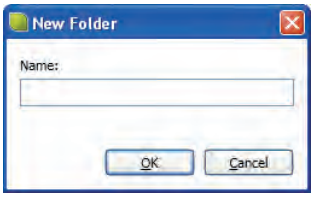


- Select a project and click **Open** to open a Project
- Click **Cancel** to close the Explore window.

3.	To create a new Folder or a new Project, right-click on desired parent Folder and select **New Folder** or **New project**.



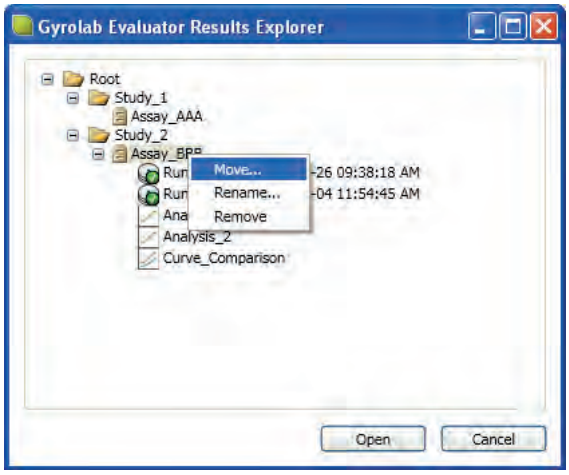
A dialog opens.



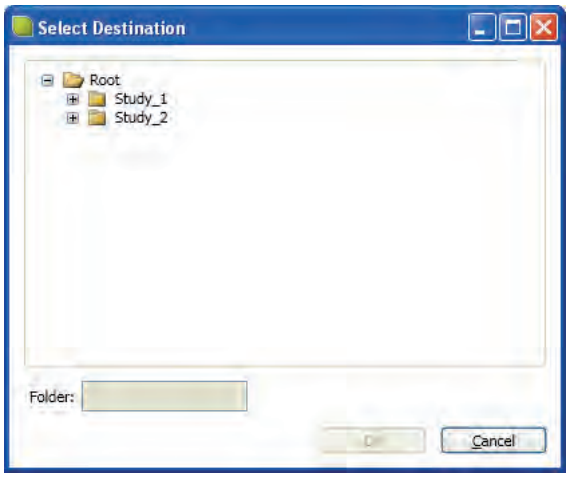
- Enter a name for the new Folder or new Project and click **OK**.
- Click **Cancel** to abort Project/Folder creation.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

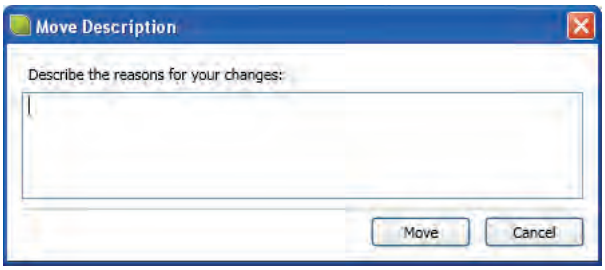
Step	Action
4.	To move an existing Folder or Project, right-click on the Folder or the Project and select **Move**.



- Select the new parent Folder and click **OK**.



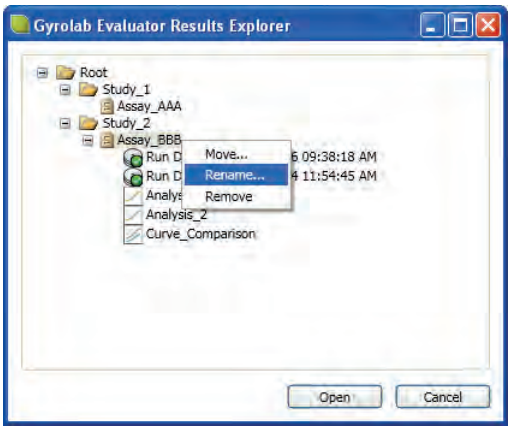
- For Projects: Enter a reason for the move. The description is saved in the Audit trail. Click **Move**.



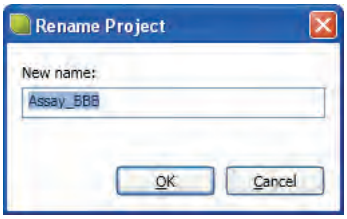
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

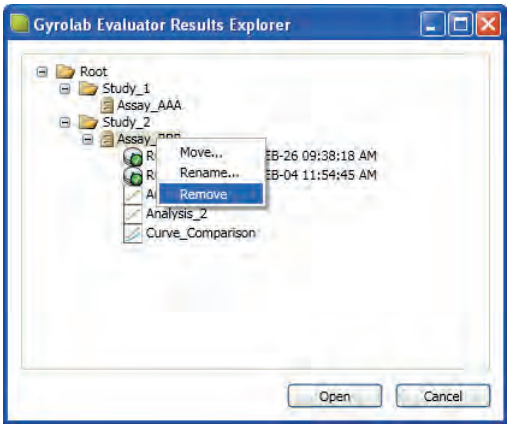
5. To rename an existing Folder or Project, right-click on the Folder or the Project and select **Rename**.



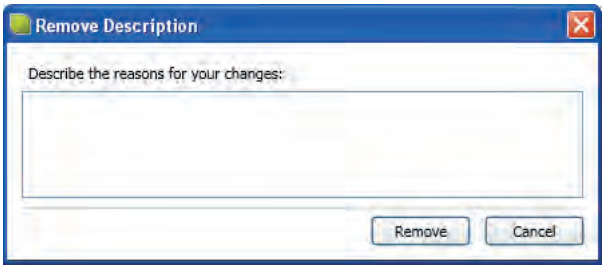
Enter the new Folder or Project name and click **OK**.



6. To remove an existing Folder or Project, right-click on the Folder or the Project and select **Remove**.



For Projects: enter a reason for the removal. The description is saved in the audit trail. Click **Remove**.

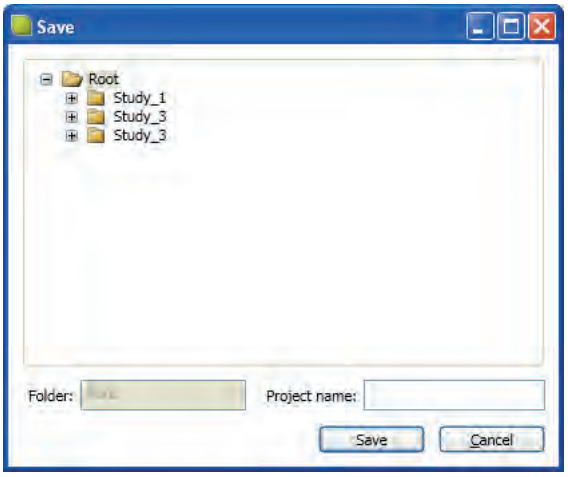


NOTE: Folders can only be removed if they are empty.

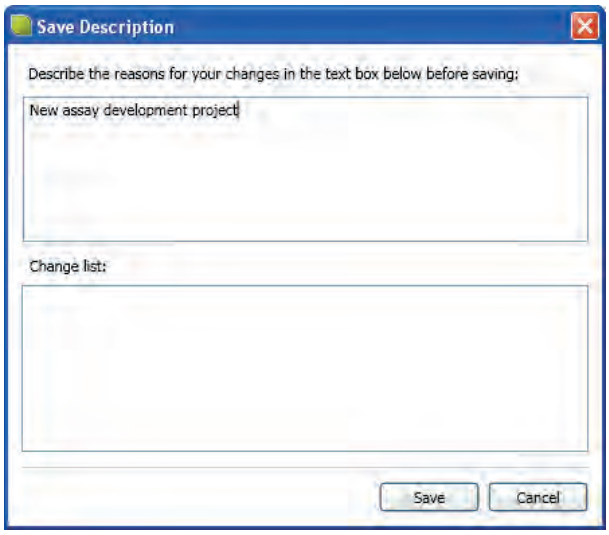
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C2.2.3.3 Create new Project

Step	Action
1.	Click **Manage** in Gyrolab Evaluator start view, and click **Create Project** in the **Manage** window.
2.	The **Save** window opens. In the folder structure in the left panel, browse to desired Folder in which the new Project will be placed, and click to highlight that Folder.



3.	Enter desired Project name in the **Name:** text box and click **Save**.
4.	The **Save Description** window opens.



5.	Enter a comment in the text box to describe the Project rationale. The comment is saved in the Audit trail.

C2.2.3.4 Edit analysis settings for Project

Step	Action
1.	Click **Manage** in Gyrolab Evaluator start view, and click **Edit Analysis Settings** in the **Manage** window.
2.	Refer to Chapter C3.8 for further instructions.

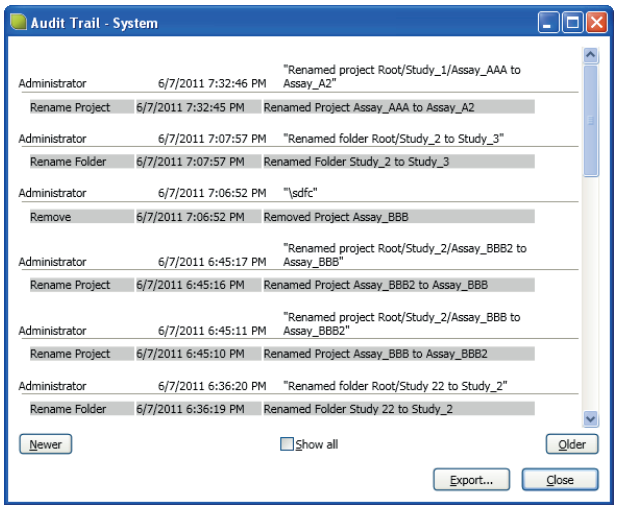
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C2.2.4 Recent Runs menu

Step	Action
1.	Click on one of the run names displayed below the **Recent Runs** headline in Gyrolab Evaluator start view.
2.	The Project view opens where the chosen Run has been added to a new Project. • For more information on the Project view and how to manage and save the new Project, refer to Chapter C3. • To perform data analysis on a Run, refer to Chapter C4.1 and Chapter C4.2 • To discard the project, click **File:Close** or the or click Close button to close the Project.

C2.3 Gyrolab Evaluator Audit trail

All system and Projects modifications are logged together with information on user identity, time and version are in the Audit trail. This is done to ensure full traceability of results. It is possible export and print Audit trail reports. This chapter describes Audit trail for Gyrolab Evaluator, refer to Chapter C3.10 for information on Project-specific Audit trail.

Step	Action
1.	Select **History:Audit trail** in Gyrolab Evaluator main view to display the Audit trail log.
2.	The Audit Trail window opens.  • To review details, click the **Open** button for desired **Project Version**. That version of the Project is opened as read-only. • To view details of an analysis click analysis expander. • To export a copy of the Audit trail in text format, click the **Export** button. Browse for desired location and click **OK**.
3.	Click **Close** to go back to Gyrolab Evaluator Project view.

Audit Trail - System
Administrator 6/7/2011 7:32:46 PM "Renamed project Root/Study_1/Assay_AAA to Assay_A2"
Rename Project 6/7/2011 7:32:45 PM Renamed Project Assay_AAA to Assay_A2
Administrator 6/7/2011 7:07:57 PM "Renamed folder Root/Study_2 to Study_3"
Rename Folder 6/7/2011 7:07:57 PM Renamed Folder Study_2 to Study_3
Administrator 6/7/2011 7:06:52 PM "\sdfc"
Remove 6/7/2011 7:06:52 PM Removed Project Assay_BBB
Administrator 6/7/2011 6:45:17 PM "Renamed project Root/Study_2/Assay_BBB2 to Assay_BBB"
Rename Project 6/7/2011 6:45:16 PM Renamed Project Assay_BBB2 to Assay_BBB
Administrator 6/7/2011 6:45:11 PM "Renamed project Root/Study_2/Assay_BBB to Assay_BBB2"
Rename Project 6/7/2011 6:45:10 PM Renamed Project Assay_BBB to Assay_BBB2
Administrator 6/7/2011 6:36:20 PM "Renamed folder Root/Study 22 to Study_2"
Rename Folder 6/7/2011 6:36:19 PM Renamed Folder Study 22 to Study_2
Newer
Show all
Older
Export...
Close

C2.4 Close Gyrolab Evaluator

Select **File:Exit**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

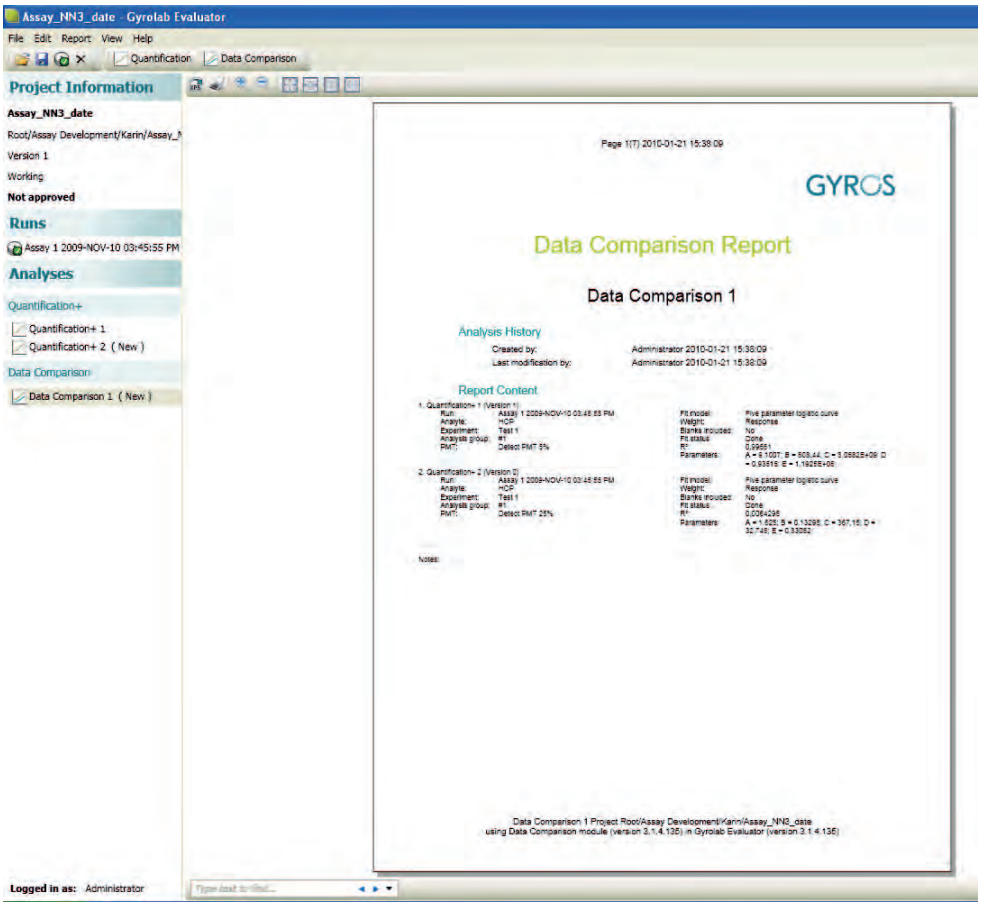
C3 Manage analysis projects

This chapter describes how to handle analysis project functionalities within Gyrolab Evaluator.

All analyses of Gyrolab Runs are organized in Gyrolab Evaluator Projects. For an introduction of how to use Projects, refer to Chapter C1.2.3.

C3.1 Project view

The Project view is reached by selecting **New Analysis** or **Open Project** in the Gyrolab Evaluator Start view described in Chapter C2. In the Project view a number of actions are available, refer to Chapter C3.2 to Chapter C3.11.2 for instructions.



- Runs in the Project are shown under **Runs**.
- Analyses in the Project are shown under **Analyses**.
- Report content for selected Run or Analysis is shown in the right part of the view. To change displayed report, select the desired Run or Analysis.

Project Information item	Name / Status (example from figure above)	Description
Project name	**Assay_NN3_date**	For Projects not yet saved the Project name is missing.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Project Information item	Name / Status (example from figure above)	Description
Folder path	**Root/Assay Development/Karin/Assay_NN3_date**	Project position in Folder structure. For Projects not yet saved the folder path is missing.
Project version	**Version 1**	Version status is increased every time the Project is saved. Version 0 is an unsaved Project.
Project status	**Working**	Project status **Not saved** for an unsaved new Project. Project status **Working** for open Projects. Project status **Replaced** for earlier versions of a Projects. Refer to Chapter C3.10 for information on how to open previous versions of a Project.
Approval status	**Not approved**	**Not approved** status is set for all active Project. **Approved** status locks the Project for further actions. Only users with user level System Administrator and Project Manager can change approval status to **Approved**, refer to Chapter F2.2.6 for more information on user levels.

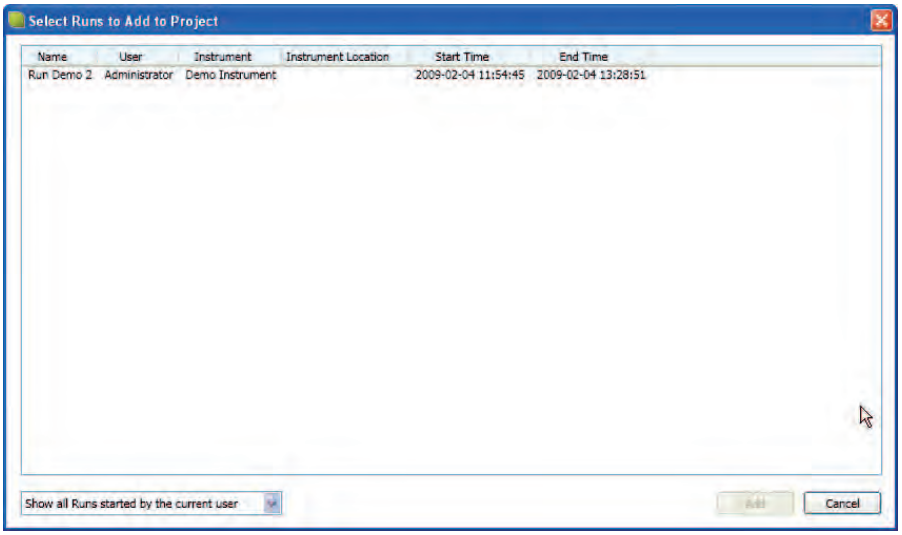
Runs	Example	Description
Run name	Assay 1 2009-NOV-10 03:45:55 PM	The Run name is generated during the Run on a Gyrolab instrument and consists of the execution name filled in before run start in Gyrolab Control and a time stamp. It can not be changed.

Analyses	Example	Note
Quantification analysis name and version	Quantification+ 1	Each quantification analysis is given a name which can be changed by the user if desired. In brackets the status is given: (nothing is shown or status New or Changed). Version number is available as a tool tip.
Data comparison analysis name and status	Data Comparison 1	Each Data comparison analysis is given a name which can be changed by the user if desired. In brackets the status is given: (nothing is shown or status New or Changed). Version number is available as a tool tip.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C3.2 Add and remove run in Project

- Click **Edit:Add Run** or the button to add a Run to an open Project.
  - A dialog opens.



  - Select one or more Runs to be analyzed in the Project and click **Add.**
  - Unselect a Run by clicking on the name again.
  - Use the list in the down left corner to view different subsets of Runs or all available Runs.
- Select a Run in the **Runs** list and click **Edit:Remove Selected Run** to remove a Run from a Project.

C3.3 Add, remove and export analyses in a Project

- To add analyses to the project, click **Quantification**

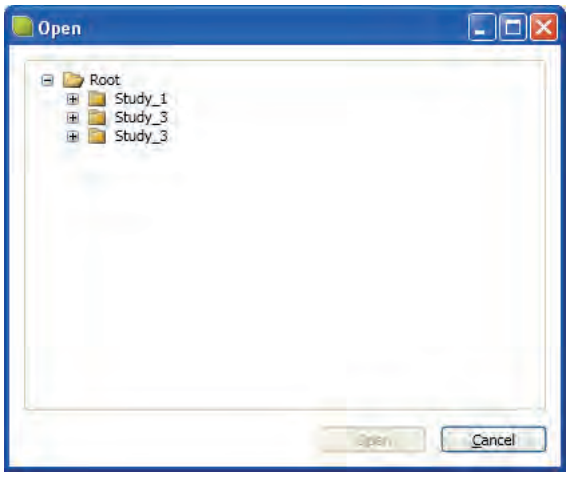
(refer to Chapter C4.1) or click **Data Comparison**

(refer to Chapter C4.2).
- To remove an existing analysis from a Project, select the Analysis in the **Analyses** list and select **Edit:Remove Selected Analysis**. This action requires System Administrator or Project Manager user level privileges.
- To export (save to file) an existing analysis, select the Analysis in the **Analyses** list and select **File:Export Selected Analyses**. To perform this step the Project must be saved. All modifications are logged in the Audit Trail.

NOTE: ***No further traceability of the file and data is supported by the Gyrolab system when analysis is exported.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C3.4 Open a Project

Step	Action
1.	In the project view, select **File:Open Project** or click .
	NOTE: ***The Open Project dialog is also available from the Gyrolab Evaluator start view.***
2.	The **Open** window opens. In the folder structure in the left panel, browse to the Folder in which the desired Project is present.
	
3.	Click to highlight Project name in the right panel and click **Open**.

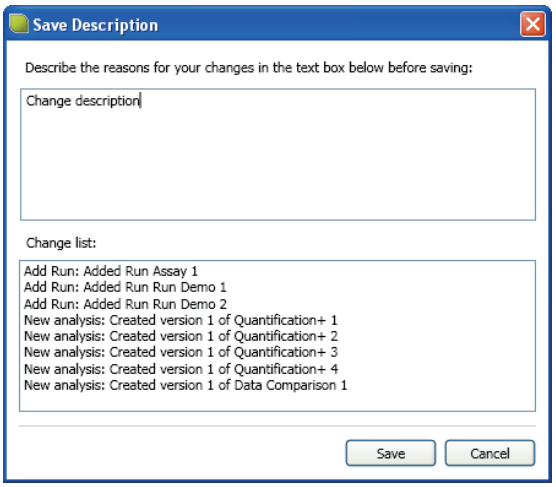
C3.5 Save a Project

NOTE: ***If no change has been made in a Project it is not possible to save it.***

Step	Action
1.	In the Project view select **File:Save Project** or click .
2.	The **Save Description** window opens.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
3.	Enter a comment in the text box to describe the reasons for Project changes. The comment is saved in the **Audit trail**.


Save Description
Describe the reasons for your changes in the text box below before saving:
Change description
Change list:
Add Run: Added Run Assay 1
Add Run: Added Run Run Demo 1
Add Run: Added Run Run Demo 2
New analysis: Created version 1 of Quantification+ 1
New analysis: Created version 1 of Quantification+ 2
New analysis: Created version 1 of Quantification+ 3
New analysis: Created version 1 of Quantification+ 4
New analysis: Created version 1 of Data Comparison 1
Save
Cancel

4. Click **Save**.

C3.6 Close a Project

Step	Action
1.	In the Project view select **File:Close** or click .
2.	If the Project has unsaved changes the **Save Project** dialog opens. • Click **Yes** to save changes. The **Save Description** window opens, refer to Chapter C3.5. • Click **No** if the changes are not to be saved.

C3.7 Approve/Unapprove a Project

Approved Projects are locked for further action. It is possible to open it but no new analyses can be saved. To approve a Project user level Project Manager or System Administrator is required.

Approved projects can be unapproved. It is possible to edit unapproved Projects. To unapprove an approved Project user level System Administrator is required.

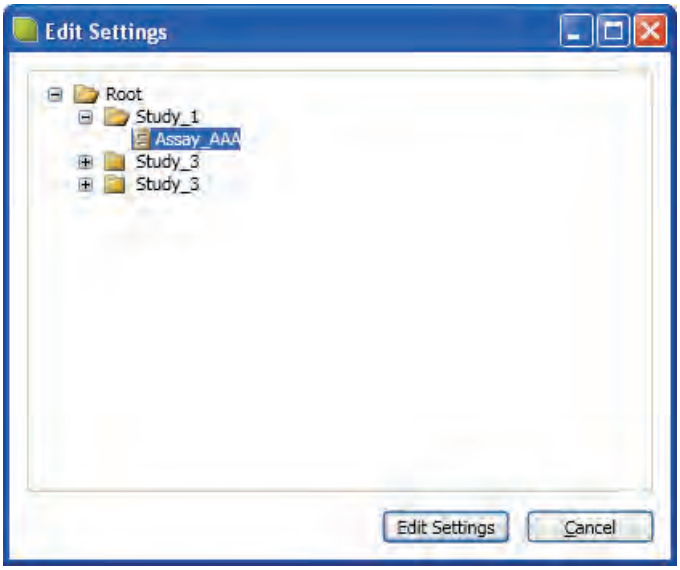
- Select **Edit:Approve Project** to approve a project. The action is logged in the system audit trail (Chapter C2.3).
- Select **Edit:Unapprove Project** to unapprove an approved project. The action is logged in the system audit trail (Chapter C2.3).

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C3.8 Set analysis settings for a Project

Analysis settings for a Project determines the default settings for data evaluation for all analyses within the Project. It is possible to lock analysis settings for a Project. This will facilitate that all analyses performed within the Project are carried out in a consistent manner.

Step	Action
1.	• To edit and set analysis settings for a Project already opened, click **View:Analysis Settings** and follow step 5 to step 10 below. • To edit and set analysis settings for a Project not opened, click **Manage** in Gyrolab Evaluator start view and follow step 2 to step 10 below.
2.	Click **Edit Analysis Settings** in the **Manage** window (The Manage window is available from Gyrolab Evaluator main menu). The **Edit Settings** window opens.
3.	In the folder structure, browse to the Folder that contains the Project for which analysis settings are to be changed and click to highlight that Folder.
4.	Click to highlight desired Project. Click **Edit Settings**.

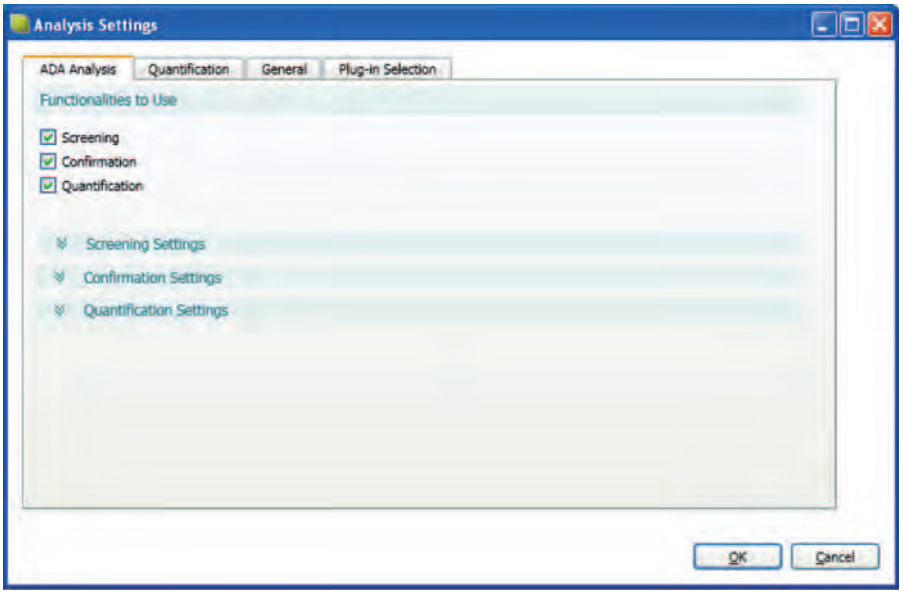


© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

5. The **Analysis Settings** window opens showing a number of tabs.

The ADA Analysis tab is specific for and only used with the software module Gyrolab ADA Software.

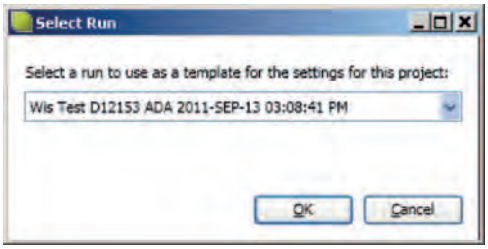


- **Functionalities to use:** Mark check boxes to select what ADA analyis functionalities to be available in the specific project.
- **Screening settings, Confirmation Settings and Quantification Settings:** Refer to Chapter D2.4 for information on analysis settings.

  To import the settings used in a previous run:

  - Click **Template Run** button

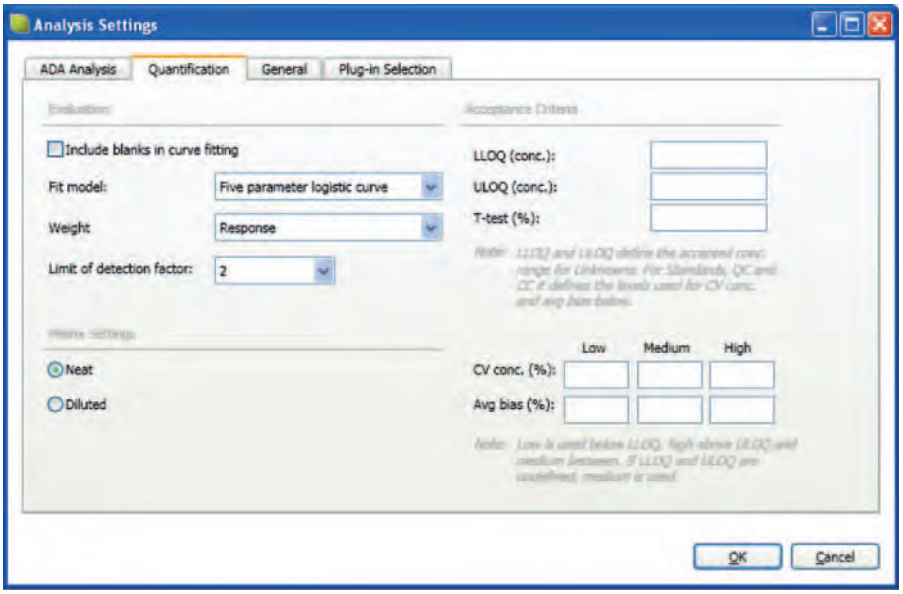
 in respective analysis section.
  - Select a run from which to import analysis settings for the project.


Select Run
Select a run to use as a template for the settings for this project:
Wis Test D12153 ADA 2011-SEP-13 03:08:41 PM
OK
Cancel

  - Select **OK**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
6.	In **Quantification** tab, edit settings for the quantification module.



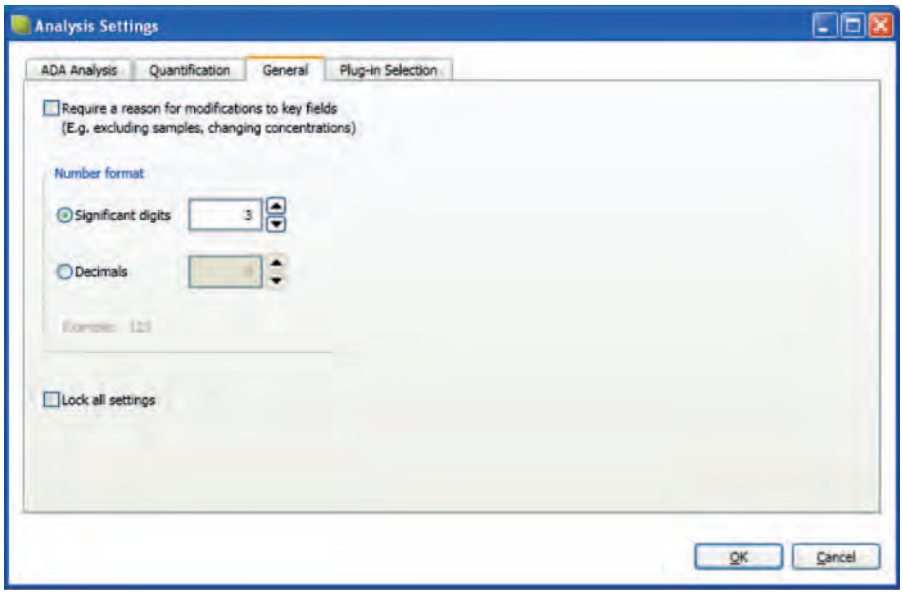
- **Evaluation:** These settings affect curve appearance and limit of detection factor.
- **Matrix Settings:** Specify if the acceptance criteria **LLOQ** and **ULOQ** refers to the back-calculated **Neat** concentration values or the **Diluted** concentration values.
- **Acceptance criteria:** These settings are used to determine which result values are considered acceptable. Result that fall outside of acceptance criteria will be highlighted in the result report.

For detailed descriptions of analysis settings for the Quantification module, refer to Chapter C4.4.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

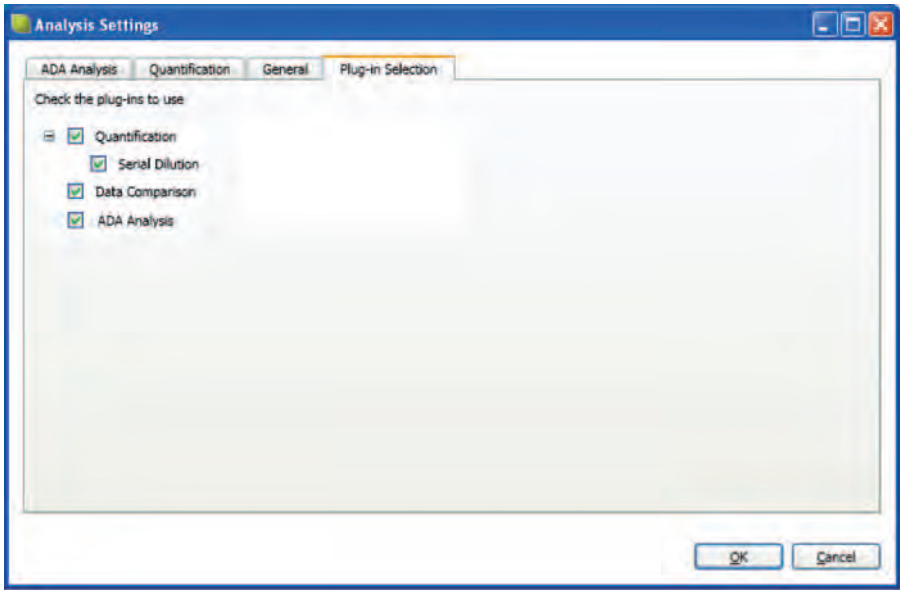
Step	Action

7. In **General** tab, edit general project settings.



- If **Require a reason for modification of key fields** box is ticked, a change description is required if a sample is excluded or included and if concentration or dilution values are changed. The change descriptions are included in the **Audit Trail**.
- Significant digits or number of decimals can be set for the current Project.
- If **Lock all settings** box is ticked, the Analysis settings are locked for all analyses within the project and for all users. Only users with user level System Administrator can edit Analysis settings or change **Lock all settings** status.

8. In **Plug-in Selection** tab, mark the check-boxes to select what software modules and plug-ins to be available in the specific Project.



9. Click **OK**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
10.	The **Save Description** window opens. • Enter a change description in the text box. • Click **Save**. The settings made will be applied on all new analyses made within the selected Project.

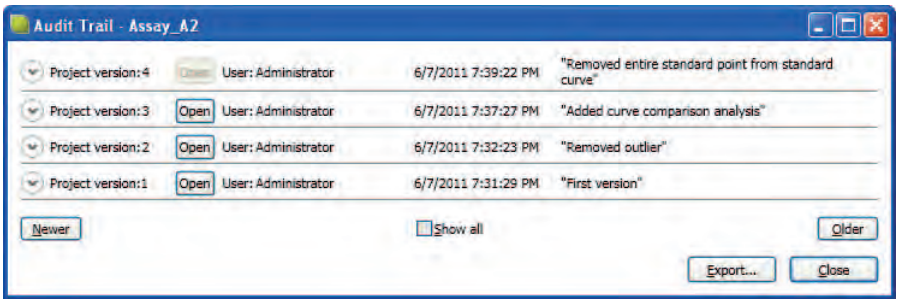
C3.9 Manage Folder structure

Projects are saved in a Folder structure. Only user with user levels Project Manager or System Administrator can make changes in the folder structure. Refer to Chapter C2.2.3 for more information on Folder structure.

C3.10 Audit trail for Projects

All Projects modifications, for example adding/removing Runs, changing Run data with analysis modules etc, are logged together with information on user identity, time and version in the Audit trail. This is done to ensure full traceability of results. It is possible export and print Audit trail reports. This chapter describes Audit trail for Projects, refer to Chapter C2.3 for information on Audit trail for the Gyrolab Evaluator.

Step	Action
1.	Select **View:Audit trail** in Gyrolab Evaluator Project view to display the Audit trail log.
2.	The **Audit Trail** window opens.



- To review details, click the **Open** button for desired **Project Version**. That version of the Project is opened as read-only.
- To view details of an analysis click analysis expander.
- To export a copy of the Audit trail in text format, click the **Export** button. Browse for desired location and click **OK**.

3.	Click **Close** to go back to Gyrolab Evaluator Project view.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C3.11 Reports and report data export

C3.11.1 Report content

A Run report contains:

- Run name and other Run information.
- Unprocessed data (raw data)
- Version number of the Gyrolab Evaluator
- Version number of the analysis module

An Analysis report contains:

- Analysis name
- Processed data (analyzed data such as Standard curve, quantification data, sample results)
- User-created analysis
- Version number of the Gyrolab Evaluator
- Version number of the analysis module

C3.11.2 View, print and export report data

Step	Action
1.	Select desired Run (available Runs are shown under **Runs**) or desired analysis (available analyses are shown under **Analyses**).
2.	To include all available sample information in the report, select **Report:ViewTables** (Run report only).
3.	The selected Run/Analysis report is shown in the right part of Gyrolab Evaluator Project view

GYROS
Run
Assay 1 2009-NOV-10 03:45:55 PM
Run information
Date and time 2009-11-10 15:45:55
Run by Administrator
Method Bioaffy 200 3-step C-A-D.wiz v1
Design type Wizard
Sample list S:\FAS\Temp xPII\Sample_list short HCP Assay 1.xls
Reagent list BioaffyReagentList
Transfer list BioaffyTransferList
Detect operations Detect PMT 1% processing: Not available
Detect PMT 5% processing: Not available
Detect PMT 25% processing: Not available
Instrument name sekuppra015
Database name GYROLAB_DB
Gyrolab Control version 5.1.0

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
4.	Use the following buttons to view the report: Zoom in. Zoom out. View Report in actual size. View Report in maximal width. View one page of the report at the time. View two pages of the report at the time.
5.	Use the search field to find specific parts of the report. Several search options are available by clicking the black arrow.
6.	Select **File:Print Selected Report** or click button to print the report.
7.	Select **File:Save report as Xps...** or click on button to export the report to **.xps**-format (Microsoft's electronic paper format). ***NOTE:*** ***When analyzing data in Quantification or Data Comparison modules it is possible to export the data to .xls or XML format, refer to Chapter C4.1 and Chapter C4.2.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C4 Analyze data

C4.1 Quantification module

The **Quantification** module is used to quantify samples by analyzing results from Gyrolab Runs. Several evaluation functions and setting options are available to achieve optimal quantification results. For an introduction to quantification analyses of Gyrolab Runs, refer to Chapter C1.

To set analysis parameters and/or to lock the settings for a Project, refer to Chapter C3.8. Analysis parameters can also be set or modified during the quantification analysis procedure, refer to step 2 below.

Step	Action
1.	In Gyrolab Evaluator Project view (Chapter C3.1), click the **Quantification** button .
2.	The **Quantification:Analysis Setup** window opens.

- In the **Runs** section, select desired Run for quantification analysis.
- In the **Analysis Settings** section, set or edit Analysis setting for Evaluation, Matrix Settings and Acceptance Criteria, refer to Chapter C4.4 for more information
- Click the **Continue** button.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

3. The **Quantification** window opens.

4. The left panel of the Quantification window displays available experiments in the run. Click on the plus or minus signs in the tree to expand or collapse the tree structure. Experiment data is structured according to:

Run name

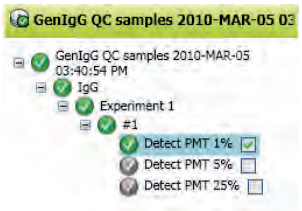
Analyte name

Experiment name

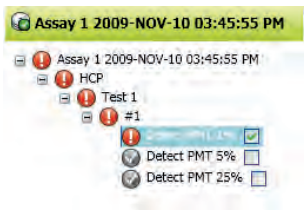
CD number (#1, #2 etc.)

Available PMT setting (Detect PMT X%)

- Green symbols (see below) indicate that the standard curve fit succeeded.



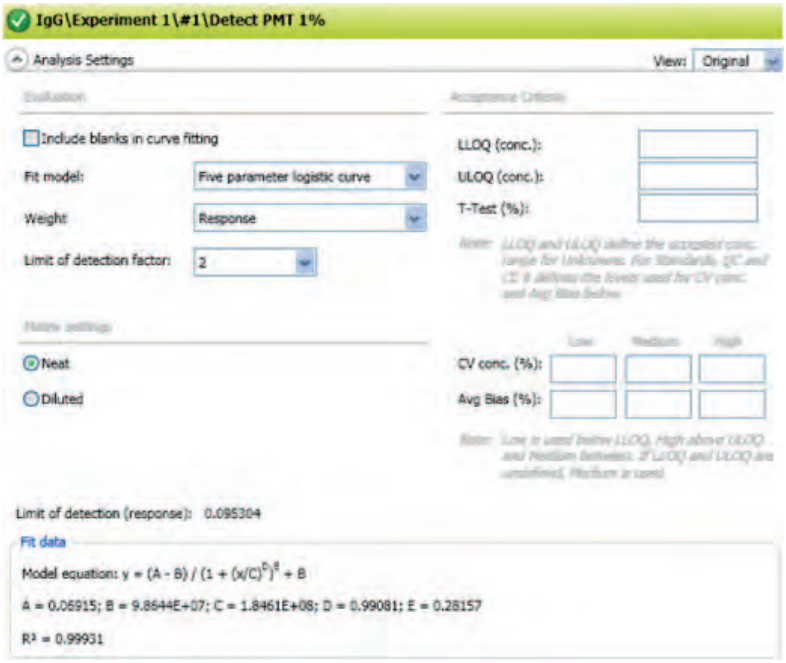
- Red symbols (see below) indicate that the standard curve fit failed.



- Click on the rows with green or red symbols to view results from corresponding data set (bottom level in the tree) in the right panel, refer to steps 6–10.
- Click the tick box of one or more experiments (bottom level in the tree) to include that/those experiments in the report.

Click **Run Info** in the bottom of the left panel to display run information such as user and date.

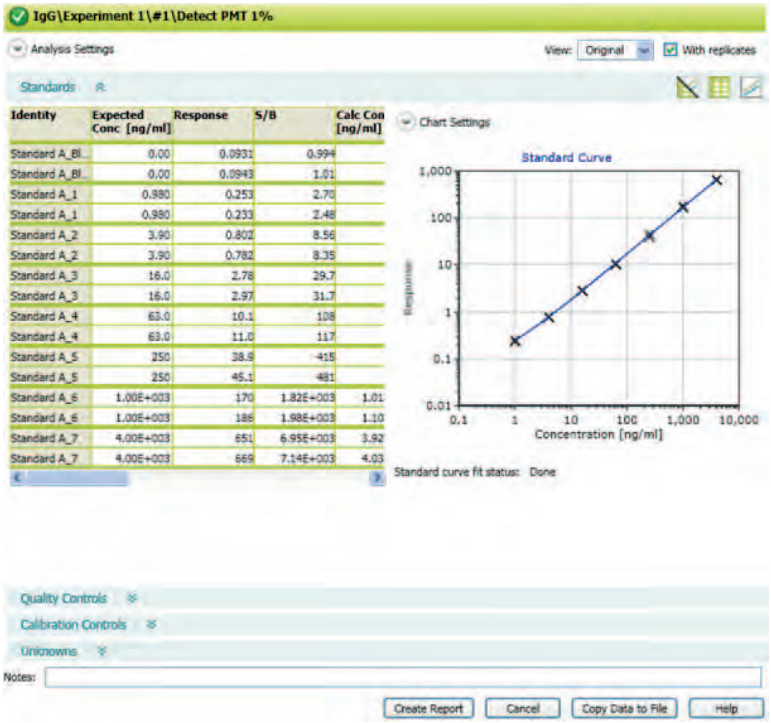
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
5.	The right panel of the Quantification window displays collapsable/expandable views for • **Analysis settings,** used to view and edit analysis settings, refer to step 6 • **Standards**, which hold standard curve data table and corresponding graph, refer to step 8 • **Quality Controls**, **Calibration Control** and **Unknowns**, which hold result data tables refer to steps 9 to 11. Other available functionalities: • Options for viewing of data tables and graph, refer to step 7 • Notes, refer to step 12 • Data export, refer to step 13 • Report generation, refer to step 14 to 16.
6.	Click **Analysis Settings** (in the right panel) to view and/or edit **Evaluation** and/or **Acceptance Criteria** settings for the analysis, refer to Chapter C4.4 for information on settings parameters. If changes are made only settings for currently opened data set will be changed. The calculated **Limit of detection** as well as **Fit data** parameter values are displayed in the bottom of this view.  Click **Analysis Settings** again to collapse the **Analysis Settings** view.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

7. General commands for **Standards**, **Quality Controls**, **Calibration Control** and **Unknowns** tables.



- In the **View** list, select display option for data tables:
  - **Original**: A selected number of data columns (default)
  - **Extended**: All available data column
- Refer to Chapter C4.3 for description of data table columns.
- If the **With replicates** box is ticked (default) all replicates for samples are shown. Untick the box to display average values for samples.
- To exclude a data point, right click on the sample and select **Exclude**. To perform this **With replicates** must be ticked. If required by Project settings, the reason for exclusion must be specified. The change description is included in the Audit Trail.
- To include an excluded sample, right-click on the sample and select **Include**. To perform this **With replicates** box must be ticked. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
- It is possible to edit **Expected Concentration** and **Dilution** values. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
- It is possible to add notes for individual samples in the right-most column if **With replicates** box is ticked and **View** list is set to **Extended**.

NOTE: ***The number and titles of columns may differ depending on the Run and if replicates are shown or not.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

8. Click **Standards** to view Standard samples data and Standard curve.

- Use buttons to display

  Standard samples data and Standard curve

  Standard samples data

  Standard curve.

- Standard Samples that fail acceptance criteria are highlighted in the table (Acceptance criteria were set in 6).
- Click **Chart settings** above the **Standard Curve** to set linear/logarithmic scales on the X-axis and the Y-axis. Click again to close the **Chart settings** window.
- Standard Curve zooming: Zoom in by clicking in the graph and drag the cursor down and right to select area with the rectangle. Zoom out by clicking in the graph and drag the cursor up and left. The original graph will be shown.
- Standard points can be excluded/included by clicking in the graph. Right-click on the point and chose **Exclude**/**Include**. The graph and the data will be updated.
- Click **Standards** again to close the **Standards** view.

9. Click **Quality Controls** to view Quality Control samples data.

- If desired: Exclude/include samples and make notes as described in 7.
- Click **Quality Controls** again to close the **Quality Controls** view.

10. Click **Calibration Controls** to view Calibration Control samples data.

- If desired: Exclude/include samples and make notes as described in 7.
- Click **Calibration Controls** again to close the **Calibration Controls** view.

11. Click **Unknowns** to view Unknowns samples data and Standard curve.

- If desired: Exclude/include samples and make notes as described in 7.
- Click **Unknowns** again to close the **Unknowns** view.

12. Optional: Add general experiment comments in the **Notes** text box located at bottom of the right panel.

13. Optional: To export data from the **Quantification** module to tab separated text format (.txt) or to Excel XML spreadsheet format (.xls), click **Copy Data To File** button, browse for desired location and click **Save**.

NOTE: ***No traceability of results is achieved using Copy Data To File. A copy of a Result file is created but this can be done for example before an analysis is saved and it is NOT logged in the Audit Trail. To fulfil the requirements of 21 CFR part 11 data must be exported from a saved Project, refer to Chapter C3.5***

14. Click **Create Report** to save analysis.

15. Set **Analysis Name** and click **OK**.

16. The analysis is now saved under **Analyses:Quantification** in Gyrolab Evaluator Project view.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C4.2 Data Comparison module

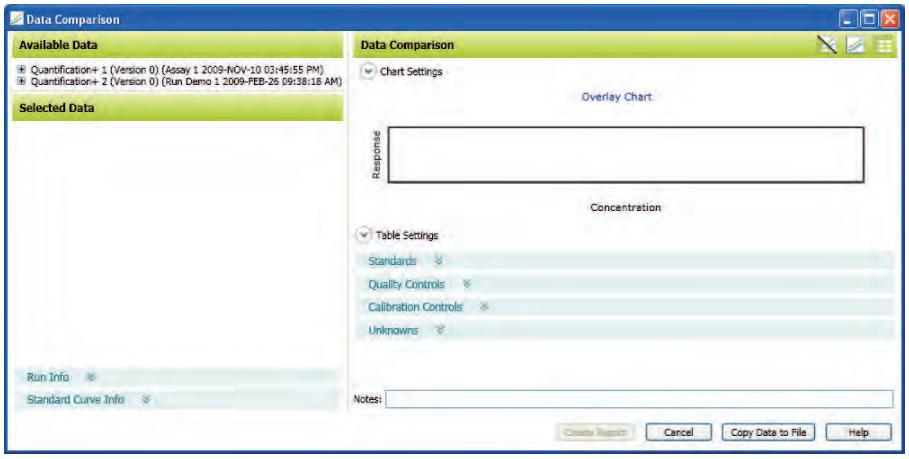
The Data Comparison module is used to compare result data and charts produced by the Quantification module for different data sets. Comparison analyses can be made between **Quantification** module analyses within a Project.

Step Action

1. In Gyrolab Evaluator Project view (Chapter C3.1), click the **Data Comparison** button

.

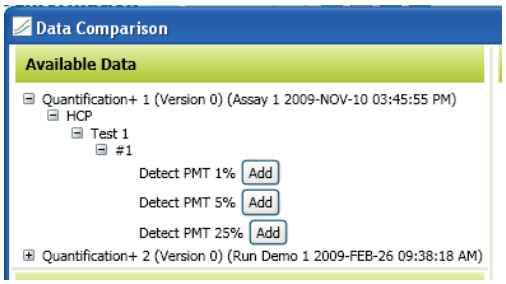
2. The **Data Comparison** window opens.



Three main panels are available:

- **Available Data**
- **Selected Data**
- **Data Comparison**

3. In the **Available Data** panel, browse and select analysis set (**Detect PMT X%** in figure below) for data comparison by clicking the corresponding **Add** button. Repeat until all desired analysis sets are selected.



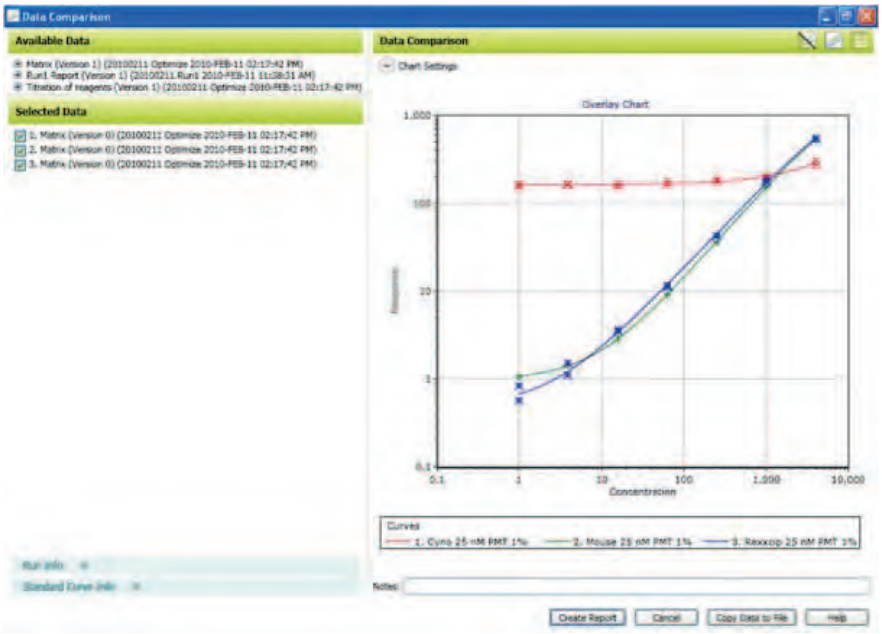
NOTE: ***The Add button will only be available if that specific analysis set is available in an Analysis Report.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

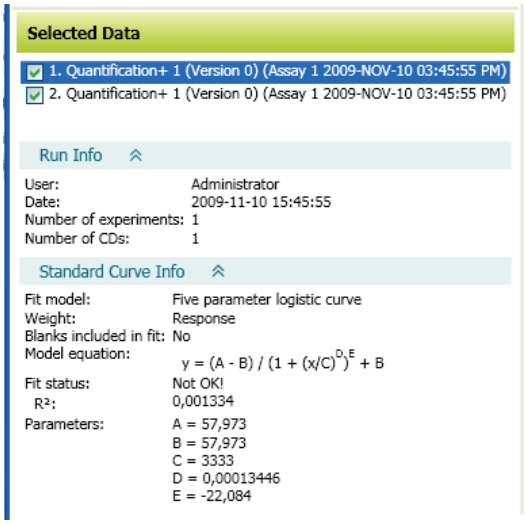
4. The selected analysis sets are listed in the **Selected Data**, information on analysis set can be found in the tool-tip. Hover with the cursor over selected data to display the tool-tip.

An overlay chart is displayed in the **Data Comparison** panel.



5. To display information for a specific analysis set:

- Click the desired analysis set in the **Selected Data** panel. The selected row in the list is highlighted.
- Click **Run Info** to display run information such as user and date.
- Click **Standard Curve Info** to display information on the analysis settings used when the quantification was performed.).


Selected Data
1. Quantification+ 1 (Version 0) (Assay 1 2009-NOV-10 03:45:55 PM)
2. Quantification+ 1 (Version 0) (Assay 1 2009-NOV-10 03:45:55 PM)
Run Info
User: Administrator
Date: 2009-11-10 15:45:55
Number of experiments: 1
Number of CDs: 1
Standard Curve Info
Fit model: Five parameter logistic curve
Weight: Response
Blanks included in fit: No
Model equation: y = (A - B) / (1 + (x/C)^D,E) + B
Fit status: Not OK!
R²: 0,001334
Parameters: A = 57,973
B = 57,973
C = 3333
D = 0,00013446
E = -22,084

6. Untick the box of a specific analysis set in the **Selected Data** panel to remove that analysis set from the **Data Comparison** panel.

Tick the box again to display the analysis set in the **Data Comparison** panel again.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

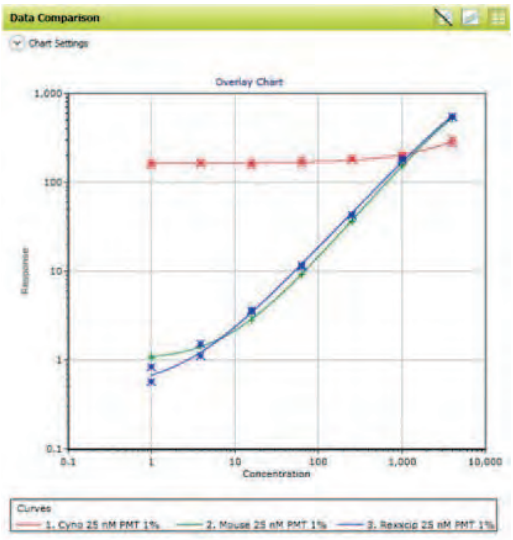
7. In the **Data Comparison** panel use buttons to display:

Samples data and overlay chart

Overlay chart

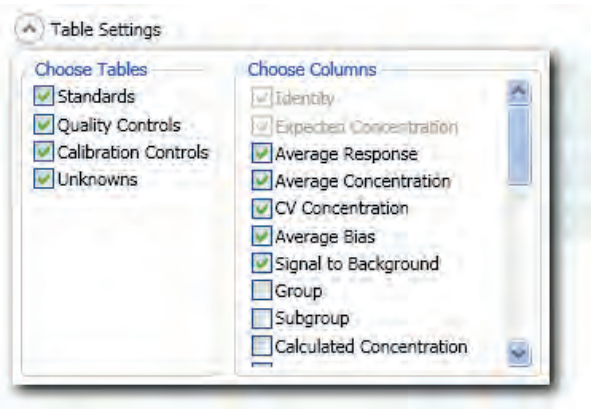
Samples data

8. **Overlay Chart functionalities:**



- Click **Chart settings** above the **Overlay Chart** to set linear/logarithmic scales on the X-axis and the Y-axis and to edit chart legend. Click again to close the **Chart settings** view.
- To rename curves, right-click on curve number and select **Rename Legend Item**. Enter new name and click **OK** (to return to default name, click **OK** directly). If the curve is not named only the number of the curve is displayed.
- **Overlay Chart** zooming: Click in the graph and drag cursor down and right to zoom in. Zoom out by clicking in the graph and dragging the cursor up and left.
- Place the cursor on a curve to display a tool-tip with the analysis settings used for that curve.

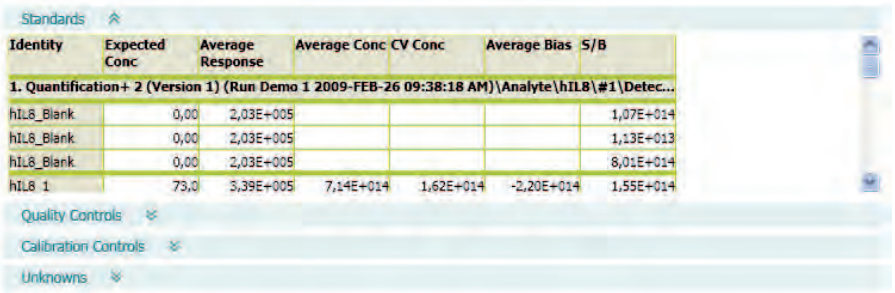
9. Click **Table Settings** to view and edit which **Tables** and **Columns** to display. Note that only selected tables and columns are included in the Report. For data columns definitions, refer to Chapter C4.4.



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

10. To view specific data points, click desired Table (**Standards**, **Quality Controls**, **Calibration Control** and **Unknowns**) to expand. Click again to collapse.



TIP: ***If not the entire name of the analysis set is visible in a Table, increase the column width, decrease number of columns, refer to step 9, or refer to complete name under Selected Data.***

11. Optional: Add general experiment comments in the **Notes** text box located at bottom of the right panel.

12. Optional: To export data from the **Data Comparison** module to tab separated text format (.txt) or to Excel XML spreadsheet format (.xls), click **Copy Data To File** button, browse for desired location and click **Save**.

NOTE: ***No traceability of results is achieved using Copy Data To File. A copy of a Result file is created but this can be done for example before an analysis is saved and it is NOT logged in the Audit Trail. To fulfil the requirements of 21 CFR part 11 data must be exported from a saved Project, refer to Chapter C3.5***

13. Click **Create Report** to save the analysis.

14. Set **Analysis Name** and click **OK**.

15. The analysis is now saved under **Analyses:Data Comparison** in Gyrolab Evaluator Project view.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C4.3 Result data table descriptions

Data table content is the same for both **Quantification** and **Data Comparison** modules.

In the **Quantification** module it is possible to choose between Original and Extended view and to view values with or without replicates. If Original view is selected the number of columns displayed may differ depending on available sample results and type of sample.

In Data comparison module replicates are always shown and it is possible to select which columns to view (however **Identity** and **Expected conc.** are always shown).

Columns displayed in the **Quantification** and **Data Comparison** modules will be included in reports generated.

If Original view is selected only columns indicated with a Yes below will be displayed. If Extended view is selected all available columns are shown.

NOTE: ***If a cell in a column is empty a value could not or should not be calculated for that cell. Examples of this is CV-calculation when only one replicate is available and for calculated concentration for a blank sample.***

Column heading	Original view	Description
Identity	Yes	Sample identity
Expected conc	Yes	Given for samples with known concentrations such as Standard Samples, Quality Controls and Calibration Controls.
Response	Yes	Integrated volume of the fluorescent binding surface of a reaction in a microstructure.
S/B	Yes	Signal to background. The ratio between the signal and the absolute value of mean of the blanks' signal.
Calc. Conc	Yes	Analyte concentration calculated from a single sample response read from a standard curve.
Average conc	Yes	The average calculated analyte concentration of replicates of a sample.
CV Conc (%)	Yes	Coefficient of variation of analyte concentration of a replicate series of a sample.
Bias (%)	Yes	Deviation from the expected value • For Calibration Controls: Bias (%) = 100 × (Calculated Concentration – Average calculated concentration for the standard sample(s)) / Average calculated concentration for the standard sample(s) • For other samples (not Unknown Samples): Bias (%) = 100 × (Calculated Concentration – Expected Concentration) / Expected Concentration
Average Bias (%)	Yes	Average Bias for a set of sample replicates.
Average Response	Yes	Average of response values for replicates of a sample, sample group or sample subgroup.
CV Response (%)	Yes	Coefficient of variation of response of replicates of a sample.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Column heading	Original view	Description
Dilution	Yes	The dilution Factor for Unknown samples and Quality Control samples. Dilution factor for Unknown samples is added in the sample list. For Quality Control samples the dilution factor is entered when setting up a Run using **Design Run** (refer to Chapter B3.1.3). The experimentally determined concentration is multiplied with the Dilution Factor to obtain the calculated analyte concentration of the neat sample. If no Dilution Factor value has been assigned a factor of 1 will automatically be used.
CD ID	Yes	Identity of Gyrolab CD microlaboratory used to process the samples.
CD Struct	Yes	Identity of structure on Gyrolab CD microlaboratory where the sample was processed.
SD Response	No	The standard deviation of responses of sample replicates.
SD Conc	No	The standard deviation of calculated concentrations of replicates of a sample.
Recovery (%)	No	Recovery is calculated for samples with known concentration: • Standard sample recovery = (Calculated concentration/Expected concentration)×100 • Calibration Control recovery = (Calculated concentration/Average concentration for the standard sample(s) with same concentration)×100 • Quality Control recovery = (Calculated concentration/Expected concentration)×100
MP Identity	No	Identity of the microplate where the sample was placed.
MP Well	No	Well position on the microplate where the sample or standard was placed.
Detect Result	No	• OK: The results are approved • Not OK: The results are not approved. The fluorescence signal is of poor quality which may be caused by inadequate PMT setting (detector is saturated) or errors in sample preparation.
Sample Type	No	Sample types: Standard, Blank, Quality Control, Calibration Control and Unknown sample
T-test	No	The T-test analyzes whether a blank and any single Standard, respectively, belong to the same data population.
Needle ID	No	The needle used to transfer the sample from the MP to the CD structure
Group	No	Optional information of important sample properties such as common source or treatment. Group is only used for Quality Control and Unknown samples (refer to Chapter B3.1.3). ***NOTE:*** ***This column is only shown for Unknown and Quality Control samples and only if there are any samples with Group information in the Experiment.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Column heading	Original view	Description
Subgroup	No	Optional information of important sample properties such as common source or treatment, which can be used to sub group samples within a group. Subgroup is only used for Quality Control and Unknown samples (refer to Chapter B3.1.3). ***NOTE: This column is only shown for Unknown and Quality Control samples and only if there are any samples with Group information in the Experiment.***
Group average conc	No	The average calculated analyte concentration of replicates of a sample group or sample subgroup. ***NOTE: This column is only shown for Unknown samples and only if there are any samples with Group information in the Experiment.*** ***NOTE: Even if a group is specified other statistical parameters is calculated for individual replicates.***
Group CV conc	No	Coefficient of variation of analyte concentration of replicates of a sample group or sample subgroup. ***NOTE: This column is only shown for Unknown and Quality Control samples and only if there are any samples with Group information in the Experiment.***
Group SD conc	No	The standard deviation of calculated analyte concentrations of replicates of a sample group or sample subgroup ***NOTE: This column is only shown for Unknown and Quality Control samples and only if there are any samples with Group information in the Experiment.***
Notes	No	It is possible to add comments to individual samples.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C4.4 Analysis settings

The finding of optimal curve fit model and other analysis settings are important for accurate calculation of results. It is possible to modify different settings and evaluate the analysis results. For example, different algorithms can be selected and outliers in Standard series can be excluded. It is recommended to use similar Settings in routine analyses as was found to be optimal during assay development.

It is possible to lock settings for a Project to ensure identical analysis settings on all samples performed within that project.

We use the Levenberg-Marquardt algorithm (LVM), which minimizes the sum-of-squares of the vertical distance between the observed data and the curve or fitted data (residuals). When weighting is used the following is minimized in order to find best curve fit.

$\Sigma\ [(Ydata - Yfit)/Weight]^2$

It can also be expressed as:

$\Sigma\ [(Ydata - Yfit)^2 \times 1/Weight^2]$

NOTE: ***Be careful using any manipulations of analysis settings and exclusions to avoid any undesired implications on reported analyte concentrations.***

NOTE: ***All changes of parameters are recorded in the Audit Trail, Chapter C3.10, to enable full traceability of results.***

Parameter	Comment
Evaluation	
Include blanks in curve fitting	Blanks included or excluded in curve fitting.
Fit model	The following fit models are available: • Five parameter logistic curve (default) • Four parameter logistic curve • Straight line • Exponential curve • MMF curve (Morgan-Mercer-Flodin) Refer to Chapter C4.4.1 for descriptions and recommendation when to use which fit model.
Weight	Following options are available: • None • Concentration • Response (default) • Standard deviation response In general a weighted fit is more appropriate than an unweighted fit.
Limit of detection factor	Following options are available: • 2 standard deviations (default value) • 3 standard deviations
Acceptance Criteria	

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Parameter	Comment
LLOQ (conc.)	Lower limit of Quantification: • For Unknown samples, the LLOQ defines the lowest level of analyte concentration measurable. • For Standards, Quality Controls and Calibration Controls, the LLOQ defines the border between Low and Medium ranges for CV conc. (%) and Average Bias (%), refer to table below.
ULOQ (conc.)	Upper limit of Quantification: • For Unknown samples, the ULOQ defines the highest level of analyte concentration measurable. • For Standards, Quality Controls and Calibration Controls, the ULOQ defines the border between Medium and High ranges for CV conc. (%) and Average Bias (%), refer to table below.
T-Test (%)	The T-test analyzes whether a blank and any single Standard, respectively, belong to the same data population.
CV conc. (%)	Coefficient of variation of concentration of replicates of a sample, sample group or sample subgroup. Set acceptance CV conc. (%) values for Standards, Quality Controls and Calibration Controls samples for: • Low: concentration values < LLOQ • Medium: concentration values from LLOQ to ULOQ • High: concentration values > ULOQ ***NOTE:*** ***For Quality Control samples the average concentration is calculated on a sample Group or sample Subgroup if there is any sample with Group information included in the Experiment.***
Average Bias (%)	Average Bias from included replicates. Average Bias is the deviation from the expected value, that is: ((Average concentration – Nominal concentration)/ Nominal concentration)×100 Set acceptance Average Bias (%) values for Standards, Quality Controls and Calibration Controls samples for: • Low: concentration values < LLOQ • Medium: concentration values from LLOQ to ULOQ • High: concentration values > ULOQ
Matrix Settings	
Neat / Diluted	Set if the acceptance criteria **LLOQ** and **ULOQ** represents the back-calculated **Neat** (i.e. 100% matrix) concentration values or the **Diluted** concentration values.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C4.4.1 Curve fit models

Dose-response curves are used to calculate concentrations of unknowns in many types of immunoassays. The X-axis shows concentration of an analyte (the substance to be studied). The Y-axis shows the fluorescent response in the assay.

Different biological results will fit to varying extent to different curve fit models. Testing different curve fit models may identify an improved curve fit. With the four parameter logistic curve, the change from the initial value and towards the final value is fairly symmetrical. When the data does not show this symmetry, the resulting fit may not be adequate. The five parameter logistic curve remedies this situation by adding an asymmetry factor.

C4.4.1.1 Four parameter logistic model

A dose-response curve with fairly symmetrical transition from one response level to another.

Model equation:

$$y = (A - B) / (1 + (x/C)^D) + B$$

Model parameters:

A: The bottom level of the curve i.e. the minimum level of y

B: The top level of the curve i.e. the maximum level of y

C: The EC50 value represents the x value at which the middle y value is attained.

D: The slope factor. A positive value is returned when y is decreasing as x increases and a negative value returned when y is decreasing as x decreases.

x: The known, original concentrations

y: The known responses

Fit Method:

Data is fitted using the Levenburg Marquardt algorithm.

C4.4.1.2 Five parameter logistic model

A dose-response curve with asymmetrical transition from one response level to another.

Model equation:

$$y = (A - B) / (1 + (x/C)^D)^E + B$$

Model parameters:

A: The bottom level of the curve i.e. the minimum level of y

B: The top level of the curve i.e. the maximum level of y

C: The EC50 value represents the x (concentration) value at which the middle y (response) value is attained for a symmetric curve (E=1).

D: The slope factor. A positive value is returned when y is decreasing as x increases and a negative value returned when y is decreasing as x decreases.

E: The symmetry factor

x: The known, original concentrations

y: The known responses

Fit Method:

Data is fitted using the Levenburg Marquardt algorithm.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C4.4.1.3 Exponential model

A curve with exponential growth.

Model equation:

$$y = Ae^{-Bx}$$

Model parameters:

A: The point where the curve crosses the y axis

B: The value of a definite physical constant

x: The known, original concentrations

y: The known responses

Fit method:

Data is fitted using the Levenburg Marquardt algorithm.

C4.4.1.4 Straight line

Linear model equation:

$$y = A + Bx$$

Model parameters:

A: Linear factor

B: Intersect

x: The known, original concentrations

y: The known responses

C4.4.1.5 MMF curve

Morgan–Mercer–Flodin curve, a sigmoidal curve with a transition from one response level to another.

Model equation:

$$y = (AB + Cx^D)/(B + x^D)$$

Model parameters:

A: The level of the curve when x approaches zero.

B: The EC50 factor. The term half maximal effective concentration (EC50) refers to the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum after some specified exposure time. It is commonly used as a measure of drug's potency. EC50 value represents the x-value at which the middle y-value is attained and is $B^{1/D}$

C: The level of the curve when x approaches positive infinity.

D: The slope factor. D is always positive, A and C values determine if y is decreasing as x increases or y is decreasing as x decreases (fitted using Levenburg Marquardt algorithm).

x: The known, original concentrations

y: The known responses

Note that the MMF curve model equation can also be expressed as:

$y = C - (C - A)/(1 + (Ex)^D)$

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C5 Gyrolab Evaluator installation on office computer

The analysis software Gyrolab Evaluator is included in the standard installation of the Gyrolab system. This chapter described how to install Gyrolab Evaluator on an office computer to enable remote evaluation of run result, eliminating the need to use the instrument computer for data analysis.

C5.1 Gyrolab Evaluator installation package

Gyrolab Evaluator installation package contains the following software:

- Gyrolab Evaluator
- Microsoft.Net Framework 4
- Gyrolab User Guide
- Software installation instructions
- Adobe Reader (enables access to Gyrolab User Guide and Software installation instructions)

C5.2 Computer requirements

Gyrolab Analysis Software Package should be installed on a computer with access to desired Gyrolab instrument.

- Preferred computer system specifications are 3 GHz processor and 1 Gb RAM memory.
- Operative system requirement is Windows 7, 32 or 64 bit.
- Minimum monitor 1024×768 resolution, medium color quality (16 bit).

C5.3 User level requirements

Installation of Gyrolab Analysis Software Package requires administrator privileges on the computer.

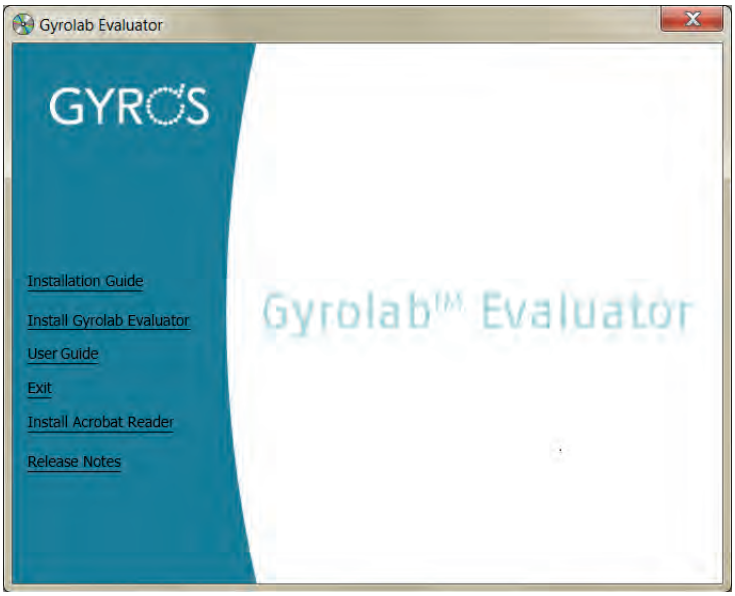
To be able to use the Gyrolab software, a user name and password is required. Contact the local Gyrolab system administrator to receive login details for Gyrolab Software.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

C5.4 Installation

Before installation start, make sure that the operating system is updated with the latest patches from Microsoft. This can be done from the web site http://update.microsoft.com/

Step	Action
1.	Insert Gyrolab Analysis Software Package CD in the CD drive.
2.	**Gyrolab Evaluator** installation screen opens.



- If the installation start screen does not appear automatically, browse for the CD folder in Windows Explorer and double-click on the file **\splash\autorun.exe**.

3.
- Select **Installation Guide** to view installation instructions.
- Select **User Manual** to access Gyrolab User Guide.
- Select **Exit** to exit installation procedures.
- Select **Install Acrobat Reader** and follow the instructions to install Acrobat Reader. This is needed only if your system does not have a pdf reader already.
- Select **Release Notes** to view information on this software release.

4. Select **Install Gyrolab Evaluator** to start installation.

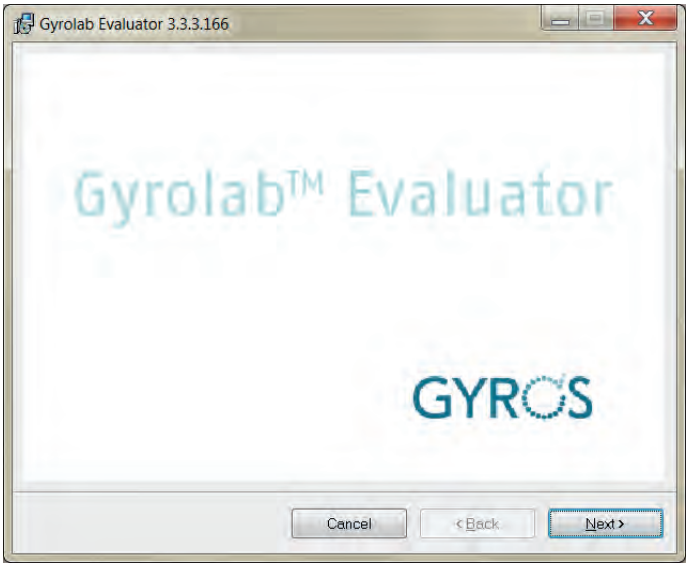
   If the installation software can not determine whether your operating system is of version 32 or 64 bit, you will be instructed on how to manually start the correct installation file.

   If .NET Framework is unavailable or of inadequate version, the installation software will also install required .NET Framework.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

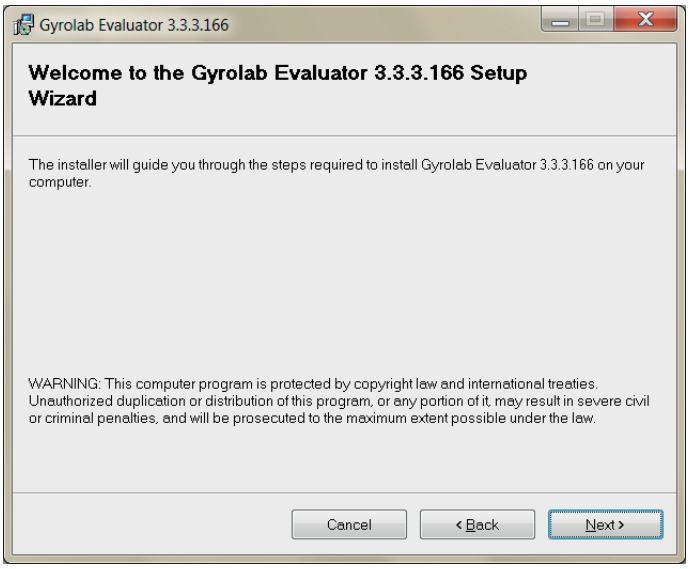
Step	Action

5. A **Gyrolab Evaluator** dialog opens. Click **Next >**.



NOTE: ***During the installation procedure it is possible to cancel installation by clicking* Cancel *and to return to previous step by clicking* < Back.**

6. A **Gyrolab Evaluator** dialog opens. Click **Next >**.


Gyrolab Evaluator 3.3.3.166
Welcome to the Gyrolab Evaluator 3.3.3.166 Setup Wizard
The installer will guide you through the steps required to install Gyrolab Evaluator 3.3.3.166 on your computer.
WARNING: This computer program is protected by copyright law and international treaties. Unauthorized duplication or distribution of this program, or any portion of it, may result in severe civil or criminal penalties, and will be prosecuted to the maximum extent possible under the law.
Cancel
< Back
Next >

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
7.	A **Gyrolab Evaluator** dialog opens. Read the license agreement, select **I Agree** and click **Next >**. If the License agreement can not be accepted click **Cancel** and contact Gyros.

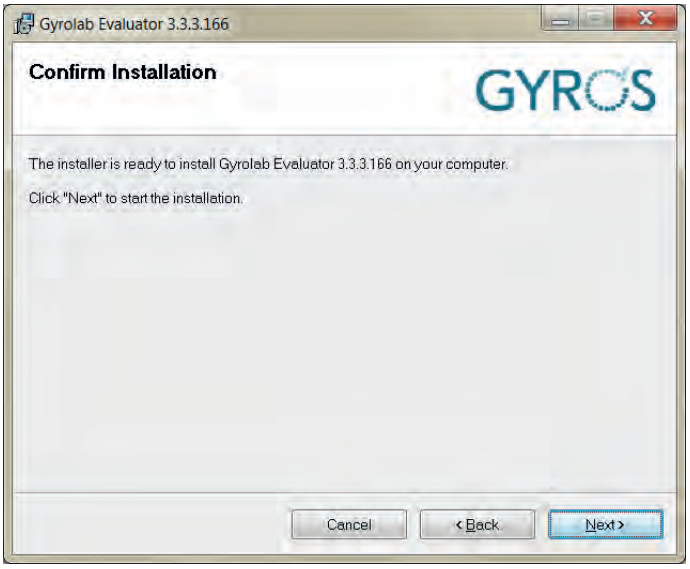
Gyrolab Evaluator 3.3.3.166
License Agreement
GYROS
Please take a moment to read the license agreement now. If you accept the terms below, click "I Agree", then "Next". Otherwise click "Cancel".
Software End User License Agreement
IMPORTANT - PLEASE READ CAREFULLY
This is the license agreement ("the Agreement") that you (the "End-User") are required to accept before installing and using the software Gyrolab Evaluator, including third party software installed using Gyros Installation Packages (the "Software"). The Software is licensed to the End-User from either: (A) Gyros AB (if the Software, the Gyrolab system and related Gyrolab products have been provided by Gyros AB or a third party
I Do Not Agree
I Agree
Cancel
< Back
Next >

8.	A **Gyrolab Evaluator** dialog opens. • Click **Browse** to select folder for installation. • Click **Disc Cost** to evaluate storage capacity to place software at certain folders. • Set user access to Gyrolab Evaluator by ticking **Everyone** or **Just me**. • Click **Next >**.

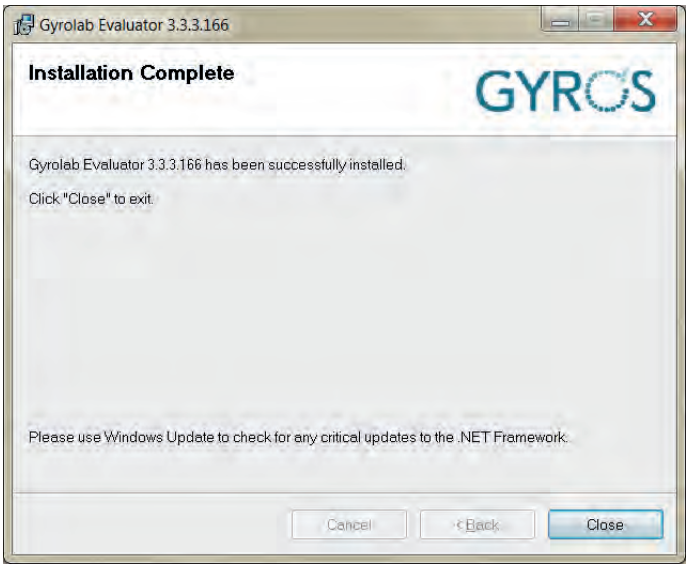
Gyrolab Evaluator 3.3.3.166
Select Installation Folder
GYROS
The installer will install Gyrolab Evaluator 3.3.3.166 to the following folder.
To install in this folder, click "Next". To install to a different folder, enter it below or click "Browse".
Folder:
C:\Program Files\Gyros\Gyrolab Evaluator 3.3.3.166\
Browse...
Disk Cost...
Install Gyrolab Evaluator 3.3.3.166 for yourself, or for anyone who uses this computer:
Everyone
Just me
Cancel
< Back
Next >

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
9.	A **Gyrolab Evaluator** dialog opens. Click **Next >** to start the installation.


Gyrolab Evaluator 3.3.3.166
Confirm Installation
GYROS
The installer is ready to install Gyrolab Evaluator 3.3.3.166 on your computer.
Click "Next" to start the installation.
Cancel
< Back
Next >

10.	When the installation is completed a **Gyrolab Evaluator** dialog opens. Click **Close** to exit.



11.	Check Windows Update for available updates for Microsoft.NET Framework 4.
12.	When the installation is finished, eject the CD.
13.	Restart the computer after installation.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

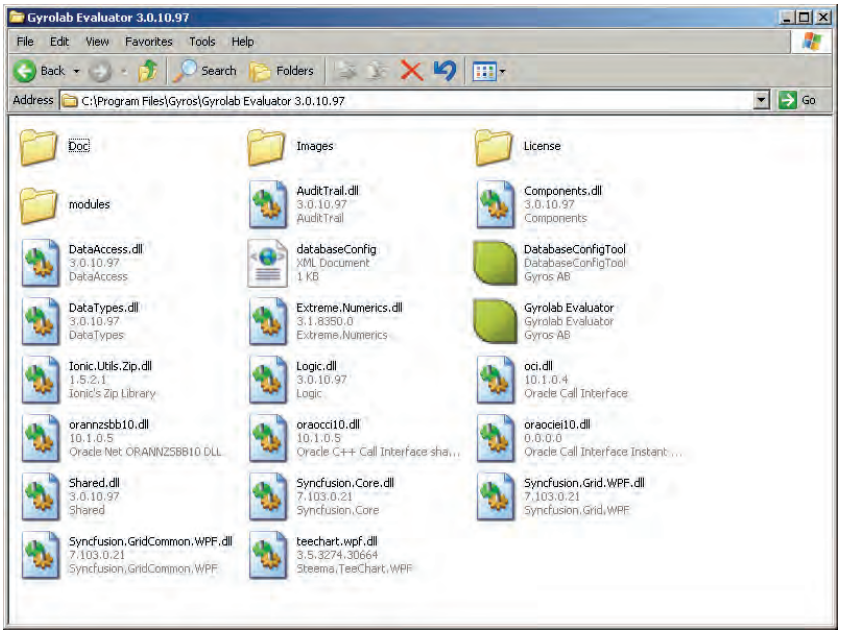
C5.5 Database configuration

Gyrolab Evaluator is designed to evaluate results processed by Gyrolab Control. The result files are stored in Gyrolab Result Database.

The Gyrolab instrument computer is installed with the Windows firewall enabled. To allow communication between the Gyrolab instrument computer and an office computer, contact the local system administrator.

This chapter describes how to configure and set up Gyrolab database communication between the Gyrolab instrument computer and another computer in the same network.

Step	Action
1.	• In Windows Explorer, browse to the Gyrolab Evaluator installation folder. The location for this folder was set during installation, refer to Chapter C5.4, step *8*. • Click to open **DatabaseConfigTool**.

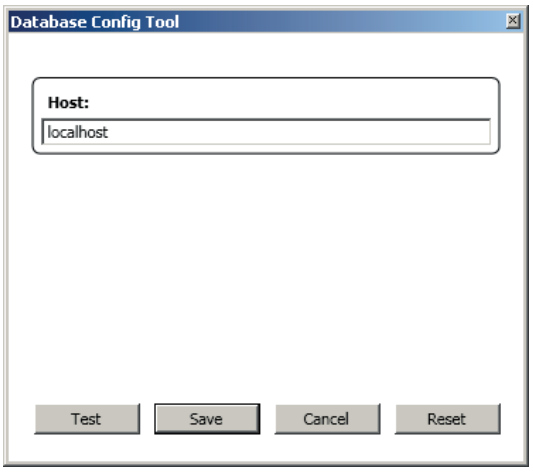


NOTE: ***Windows Vista and Windows 7 UAC (User Application Control) may not allow to select* DatabaseConfigTool. *Right-click on the* DatabaseConfig-Tool *icon (administrator user privileges required) to Right-click on the* DatabaseConfig-Tool *icon (Run as administrator) and select to allow database configuration in the dialogs that follow.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

2. The **Database Config Tool** opens:



Enter the name of the Gyrolab database in the **Host** field:

- If Gyrolab database is located on the same computer as Gyrolab Evaluator, enter *localhost*
- if the Gyrolab database is located on a different computer than the Gyrolab Evaluator software, enter the computer network address for the computer that holds the Gyrolab Result Database
- **Reset** will regenerate the original *localhost* settings.

3. Click **Save**.

4. Press the **Test** button to verify the connection. There should be no red text in the result. If there is any text, refer to Chapter G2.3

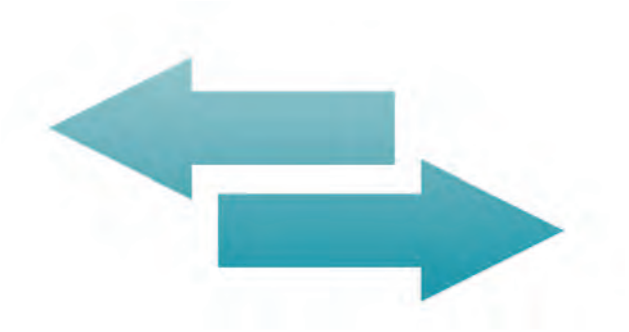
To change database, perform step 1 to 3 above and change to desired database in step 2.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

GYROLAB USER GUIDE

D Gyrolab software add-on modules



Contents

D1 Gyrolab Viewer D-5

D1.1 Gyrolab Viewer introduction D-5

D1.2 View binding profile images D-5

D1.3 Interpreting Gyrolab Viewer images..... D-10

D1.3.1 Using Gyrolab Viewer to optimize PMT setting for a run D-10

D1.3.2 Using Gyrolab Viewer to characterize binding properties.... D-11

D1.3.3 Using Gyrolab Viewer to investigate outliers..... D-11

D1.4 Installation of Gyrolab Viewer D-12

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D2 Gyrolab ADA Software D-13

D2.1 Introduction to Gyrolab ADA Software workflow D-13

D2.2 Run set-up D-13

D2.2.1 Design Method D-13

D2.2.2 Design Run D-15

D2.3 Prepare Run D-21

D2.4 Data evaluation D-24

D2.4.1 Screening D-24

D2.4.2 Confirmation D-29

D2.4.3 Quantification D-33

D2.4.4 Data export and report generation D-35

D2.5 Installation of Gyrolab ADA Software D-35

D3 Gyrolab LIMS Interface D-37

D3.1 Introduction to Gyrolab LIMS Interface workflow D-37

D3.2 Create or edit a LIMS Run D-38

D3.3 LIMS worklist generation D-41

D3.4 Prepare LIMS Run D-42

D3.5 Gyrolab LIMS Interface data output D-46

D3.6 Data evaluation D-46

D3.7 Installation of Gyrolab LIMS Interface D-46

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D4 Gyrolab Control Report D-47

D4.1 Introduction to Gyrolab Control Report D-47

D4.2 Perform run using Gyrolab Control Report D-47

D4.3 Gyrolab Control Report output D-48

D4.4 Installation of Gyrolab Control Report D-49

D5 Gyrolab Serial Dilution Analysis. D-51

D5.1 Introduction D-51

D5.2 Create Run D-51

D5.3 Perform serial dilution analysis D-52

D5.4 Gyrolab Serial Dilution Analysis data table description D-55

D5.5 Analysis settings for Gyrolab Serial Dilution Analysis D-57

D5.6 Installation of Gyrolab Serial Dilution Analysis D-58

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D1 Gyrolab Viewer

Visit www.gyros.com for the latest updates on available software modules.

D1.1 Gyrolab Viewer introduction

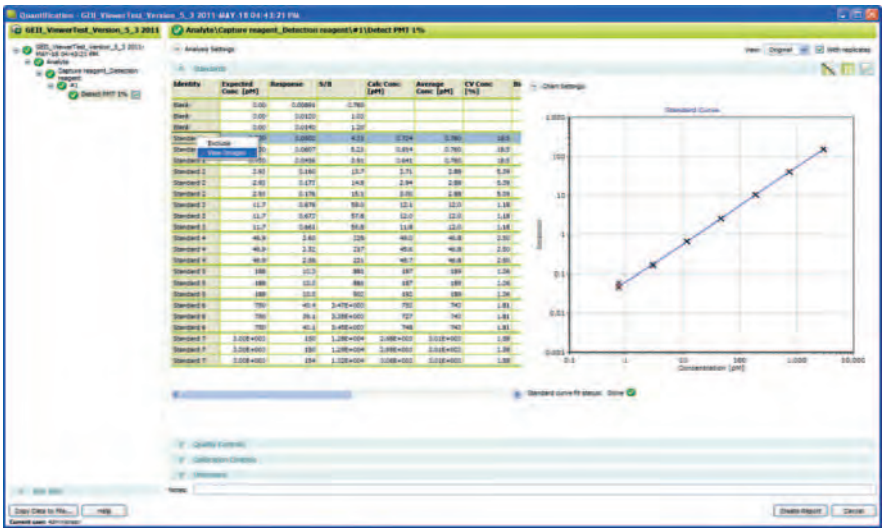
Gyrolab Viewer is a software add-on module for Gyrolab Control version 5.3 and Gyrolab Evaluator version 3.2 or higher. The module converts on-column fluorescence data into a binding profile, revealing the interaction taking place on the column within each CD microstructure. The binding profiles are accessed through Gyrolab Evaluator.

Gyrolab Viewer is used during assay development to aid in the selection of optimal reagents and during quality control and assay troubleshooting to investigate outliers.

D1.2 View binding profile images

Binding profile images are accessed through the analysis modules, for example **Quantification** or **Data Comparison.** Refer to Chapter C4.1 and Chapter C4.2 for information on Quantification and Data Comparison modules.

Step	Action
1.	In the analysis window, select a sample in a data table. Right-click on the sample identity and select **View Images...**

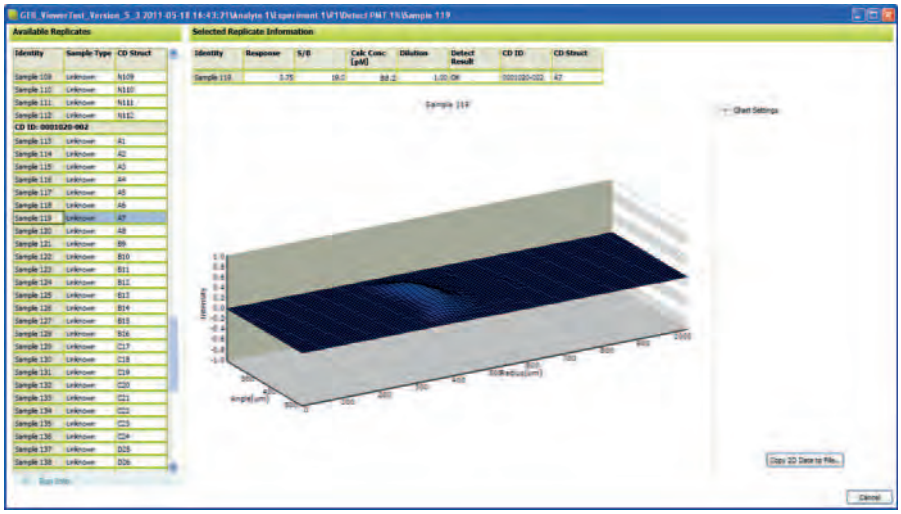


© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

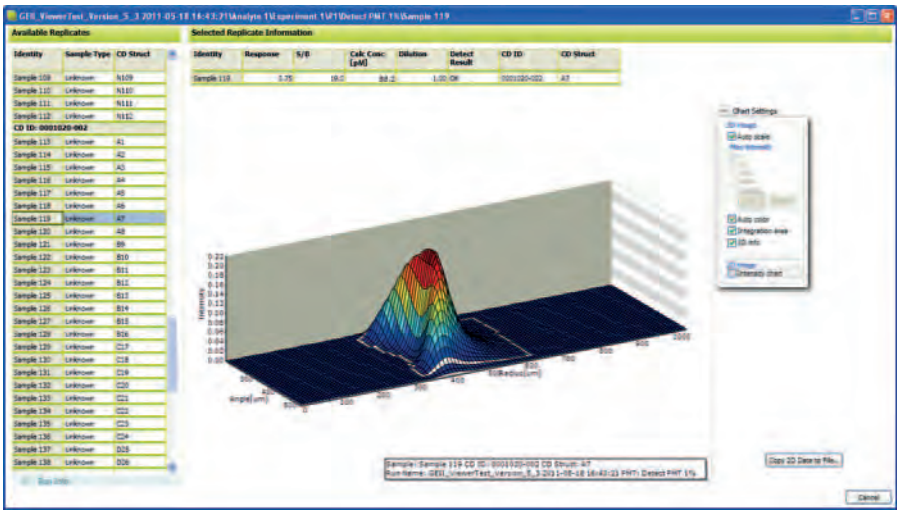
Step	Action
2.	**Gyrolab Viewer** window opens.

The binding profile is a 3D representation of the response intensity in each Gyrolab CD microstructure. The binding profile color, ranging from dark blue to dark red, corresponds to signal intensity from 0 to 1. For alternative profile coloring, refer to step 3.

For further information on binding profile interpretation, refer to Chapter D1.3.



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

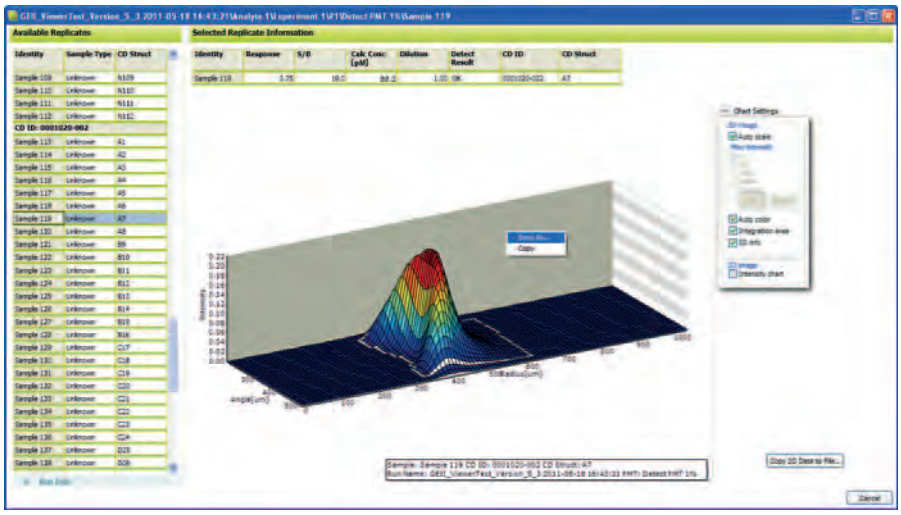
Step	Action
3.	Click within the 3D image and drag to change the view angle. To control the 3D binding profile display, click **Chart Settings...** • Select scale for the intensity axis: Choose between **Autoscale** or a fixed **Max intensity**. For fixed intensity axis, choose between default values or set a custom value. Click **Update** for the custom value change to take effect. Available intensity axis value range is 0.001 to 1. • Mark check box **Integration area** to display the integration area on top of the binding profile. The integration area illustrates what part of the signal that is included in the calculation of the sample response value. • Mark check box **Autocolor** to obtain binding profile coloring where colors range from dark blue to dark red corresponding to lowest and highest signal intensity within each specific image. • Mark check box **Show 3D info** to display a text box with sample, CD structure and run information. This text box is included in the binding profile image when copied or saved to another location. • Click **Chart Settings** again to close the settings window. 

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

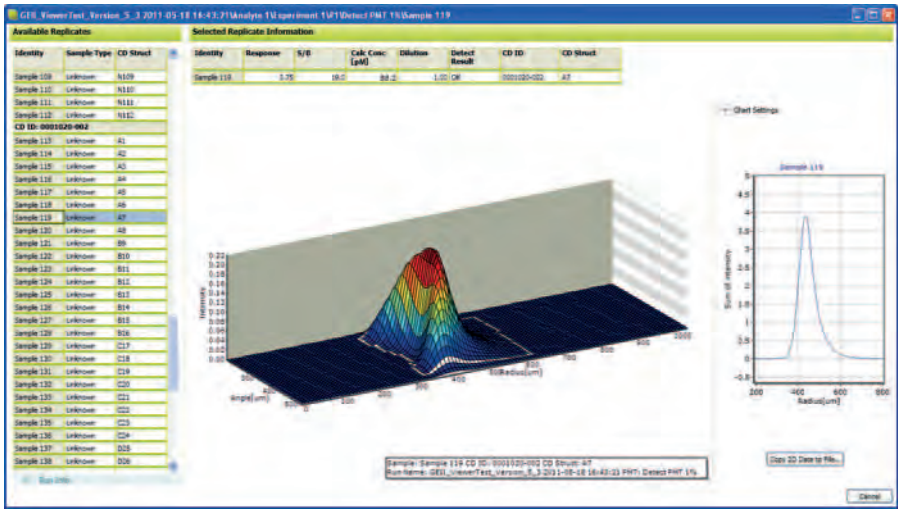
4. To copy or save the 3D image to file, right-click in the image and select:

- **Save As...** to save the 3D image to disc. In the Save As... dialog, enter desired file name and choose between available file formats (.svg, .jpg, .vml, .xaml, .gif, .png, .tiff, .bmp). Click Save.
- **Copy** to place a copy of the image on the clipboard.



5. To display a 2D image of the binding profile, click **Chart Settings...**

- Mark check box **Show Chart** in the 2D image, Intensity Sum section. Click **Chart Settings** again to close the settings window.
- A two-dimensional contour plot appears. The 2D image displays the sum of the intensity across the microstructure in radial direction.
- Zoom in by clicking in the 2D graph and drag the cursor down and right to select an area with the rectangle. Zoom out by clicking in the graph and drag the cursor up and left. The original graph will be shown.

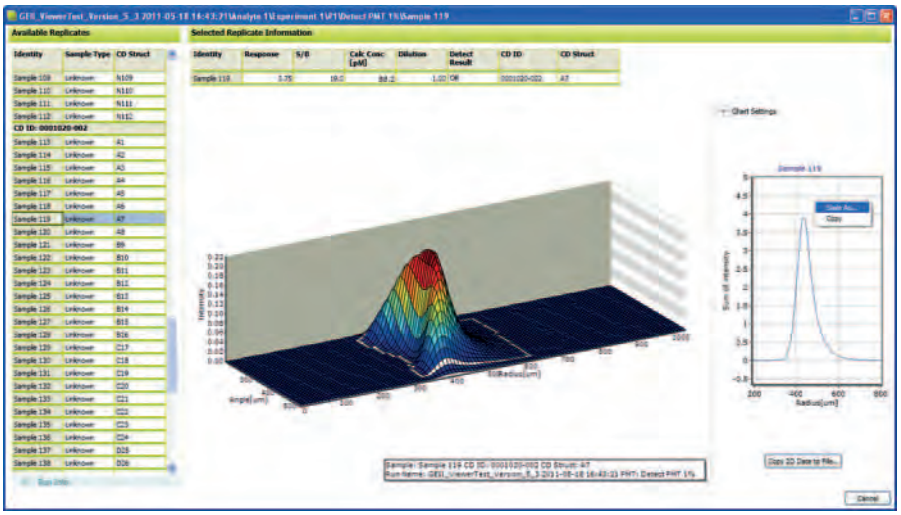


© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

6. To copy or save the 2D image to file, right-click in the image and select:

- **Save As...** to save the 2D image to disc. In the Save As... dialog, enter desired file name and choose between available file formats (.svg, .jpg, .vml, .xaml, .gif, .png, .tiff, .bmp). Click Save.
- **Copy** to place a copy of the image on the clipboard.



7. To export 2D data to file, click **Copy 2D Data To File** button. A dialog appears:

Export Data
Data will be exported to a file. Please note that no further traceability of the file and data is supported by the Gyrolab system.
OK

- The dialog is to remind the user that further analysis of the 2D image data is not supported by the Gyrolab Viewer software. Click OK.
- In the **Save As...** dialog, enter desired file name and choose between available file formats (Excel XML Spreadsheet .xls or Text file .txt). Click Save.
- The exported data can be used to create 2D overlay plots in other analysis software, for example Microsoft® Excel®.

8. Click **Cancel** to close the Gyrolab Viewer window and return to the analysis module window.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D1.3 Interpreting Gyrolab Viewer images

All interactions in the CD microstructure is generated under controlled flow conditions. The binding profiles produced by Gyrolab Viewer is a representation of the signal intensity in each Gyrolab CD microstructure and illustrates the analyte's position in the microstructure.

Interaction between the capture reagent and the analyte molecule affects profile characteristics. Characteristics of an ideal binding profile:

- The signal is not saturated, i.e. the maximum signal intensity within the binding profile is lower than 1.
- The binding profile has a sharp peak and has a narrow distribution in the radial direction, indicating high affinity between capture reagent and analyte.
- No signal spikes are visible within the binding profile.

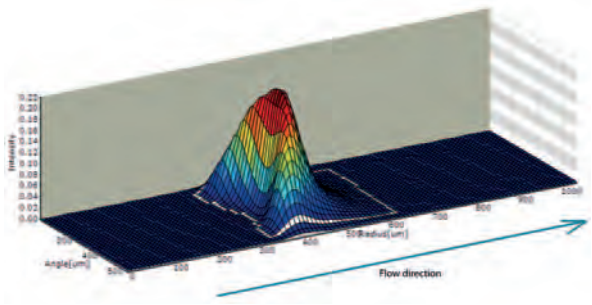


Figure 1: Example of desired binding profile in Gyrolab Viewer

D1.3.1 Using Gyrolab Viewer to optimize PMT setting for a run

The images produced in Gyrolab Viewer are useful when selecting the optimum PMT setting for a Gyrolab Run.

The fluorescent signal from the microstructure column is amplified by a photo multiplier tube (PMT) when the signal reaches the detector. The degree of amplification needed to obtain a sufficient response value depends on the signal intensity of the measured sample. The signal amplification is controlled by the PMT setting in a Gyrolab method.

Since the response signal is dependent on the analyte concentration of the sample as well as the PMT setting, combining a high analyte concentration and high PMT setting may saturate the detector. An example of a saturated signal is given in Figure 2.

To ensure proper quantification of response signal when analyzing run results, use data produced with a PMT setting that does not saturate the detector. If such results are not available within the run, rerun the assay using a lower PMT setting in the Gyrolab method.

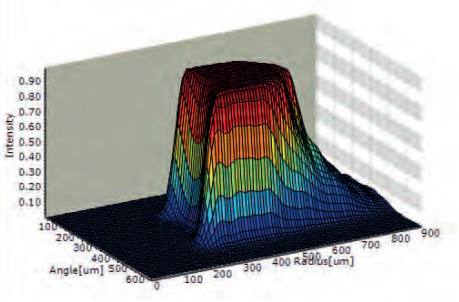


Figure 2: Example of binding profile that indicates saturated detector signal

If the calculated concentration for a sample is very low and Viewer images display low-intensity binding profiles even for samples with highest expected concentration, use data produced with a higher PMT setting. If such results are not available within the run, rerun the assay using a higher PMT setting in the Gyrolab method.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D1.3.2 Using Gyrolab Viewer to characterize binding properties

During assay development different reagents are evaluated to find the most suitable for the specific assay. In combination with evaluating standard curves and result data in Gyrolab Evaluator, the Viewer images can provide useful insights.

To achieve acceptable assay performance, reagents with appropriate affinity should be selected. When the assay is intended to measure low analyte concentrations high affinity reagents are required. For assays with a working range at higher analyte concentrations, reagents with lower affinity can be selected.

- Binding profiles where capture reagent–analyte interaction is weaker normally display a peak that is broader in radial direction i.e. the signal is more widely distributed along the flow direction in the microstructure column (Figure 3).
- Binding profiles of where capture reagent–analyte interactions are strong display sharp peaks. The reagent is more efficient in enriching the analyte in the top of the column compared to a capture reagent with lower affinity (Figure 3).

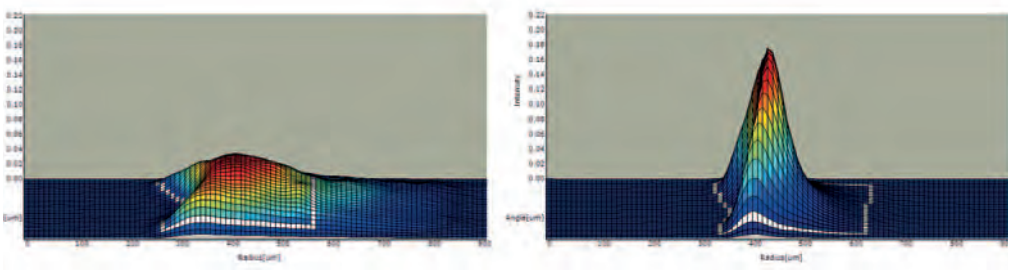


Figure 3: Example of binding profiles that indicate lower affinity (left) and higher affinity (right) between capture reagent and analyte

D1.3.3 Using Gyrolab Viewer to investigate outliers

When analyzing assay results, Gyrolab Viewer may assist in investigating outliers.

Fluorescent spikes may occur in the low end of the concentration range and affect the performance of the assay in this region. When spikes appear in the column profiles this may indicate contamination in samples, reagents or wash solutions.

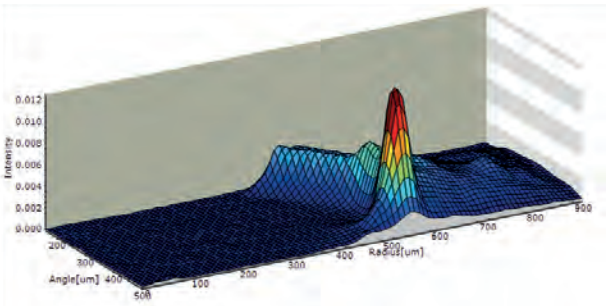


Figure 4: Example of binding profile with spike irregularities

To prevent this and similar issues it is important that all liquids entering the microstructures (reagents, samples and buffers) are prepared according to recommendations. These procedures include centrifugation, filtration and storage. Refer to Chapter B1 for recommendation on reagent labelling, Chapter B4 for recommendations on sample and reagent preparation, and to Gyrolab Instrument Guide.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D1.4 Installation of Gyrolab Viewer

The Gyrolab Viewer software module is available for Gyrolab Evaluator version 3.2 or higher and is activated by the user with a licence key. Licences are instrument specific. Contact Gyros to purchase Gyrolab Viewer and receive a license.

To register the license: Save the license file to the hard disk of the computer at a user defined destination, for example: `C:\ProgramData\Gyros\Licenses`.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D2 Gyrolab ADA Software

Visit www.gyros.com for the latest updates on available software modules.

D2.1 Introduction to Gyrolab ADA Software workflow

Gyrolab ADA Software is a software add-on module for Gyrolab Control version 5.4 and Gyrolab Evaluator version 3.3 or higher.

To enable data analysis in the Gyrolab ADA Software module in Gyrolab Evaluator, runs must be performed using the Gyrolab Mixing CD and its specific methods.

The Gyrolab ADA product portfolio enables measurement of anti-drug antibodies (ADAs) in the presence of excess amounts of drug. Samples are treated with acid in an automated procedure to allow drug-ADA complexes to dissociate, and then neutralized just before analysis, preventing complexes from reforming. The acid pre-treatment of the ADA-drug complex increases the "drug tolerance" of the assay, a term used to describe its capability to detect ADAs in the presence of drug in the sample.

Recommendations on assay development and sample and reagent preparations are found in the Gyrolab ADA assay protocol, included in the purchase of Gyrolab ADA Software.

During clinical ADA analysis samples are screened for ADA positives in a **Screening** assay. **Confirmation** assays are performed to investigate whether positive samples from screening are true positives. Evaluation functionalities are available in Gyrolab ADA Software to support these analyses.

D2.2 Run set-up

D2.2.1 Design Method

The Gyrolab Mixing CD contains 48 microstructures, all with individual mixing chambers upstream of the capture column. The mixing chamber allows for rapid mixing of liquids added according to the Gyrolab method. Mixing is followed by incubation steps to get the full effect of sample acidification to dissociate ADA-drug complexes or neutralization to form complexes necessary for detection of ADAs.

Two parameters in the ADA methods can be controlled by the user: mixing time and incubation time.

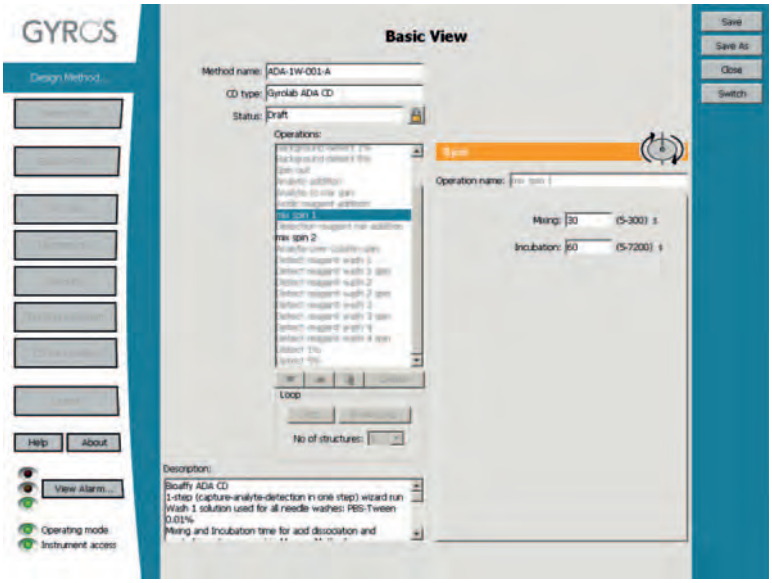
NOTE: ***User level Method Developer, Project Manager or System Administrator is required to edit methods. For more information on user levels, refer to Chapter F2.2.6.***

Step	Action
1.	In the main menu of Gyrolab Control (refer to Chapter F1.1.2), select **Methods...**
2.	Select an ADA method in the method list and click **Open...**

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

3. The **Basic View** for method editing opens.

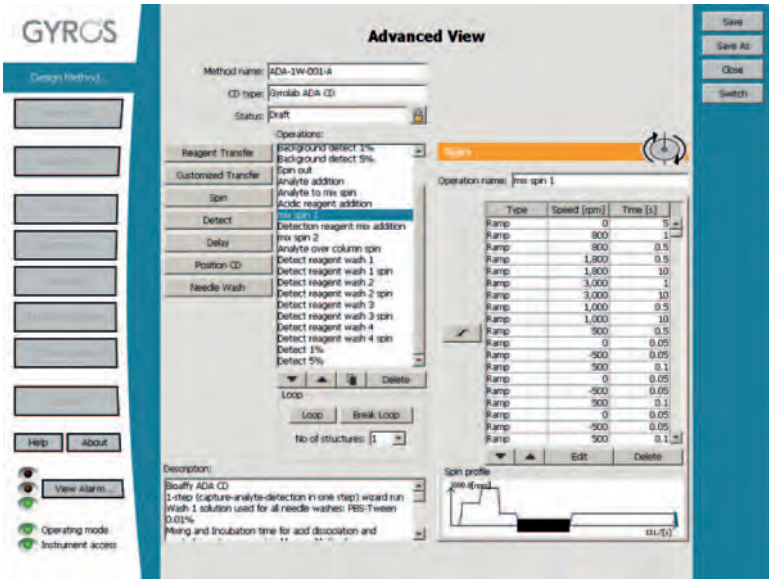


Method steps that are editable are displayed in black in the **Operations** list. Select the method step you wish to edit (in the example above mix spin 1 or mix spin 2).

Enter mixing and incubation times in seconds in the fields **Mixing** and **Incubation**.

- Click **Save** to save the method change.
- Click **Save As** to save the method in a new name.

4. To enable editing of all method steps, click **Switch**. The **Advanced View** for method editing opens.



Advanced editing is a function used for developing customized Methods to suit specific needs. Contact Gyros for more information.

5. Click **Close** to close the method editor.

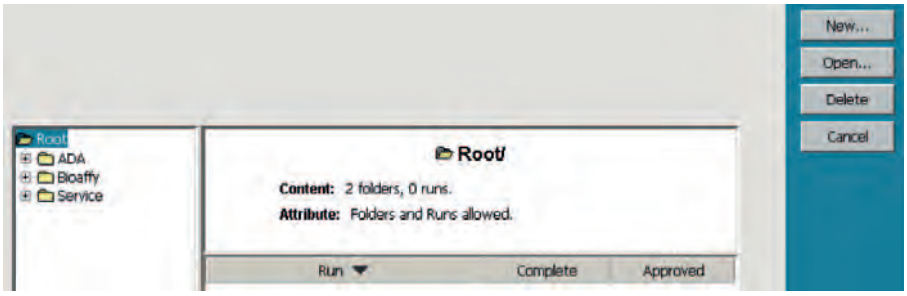
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D2.2.2 Design Run

This chapter describes how to create or edit an ADA Run using the Wizard workflow.

Step	Action

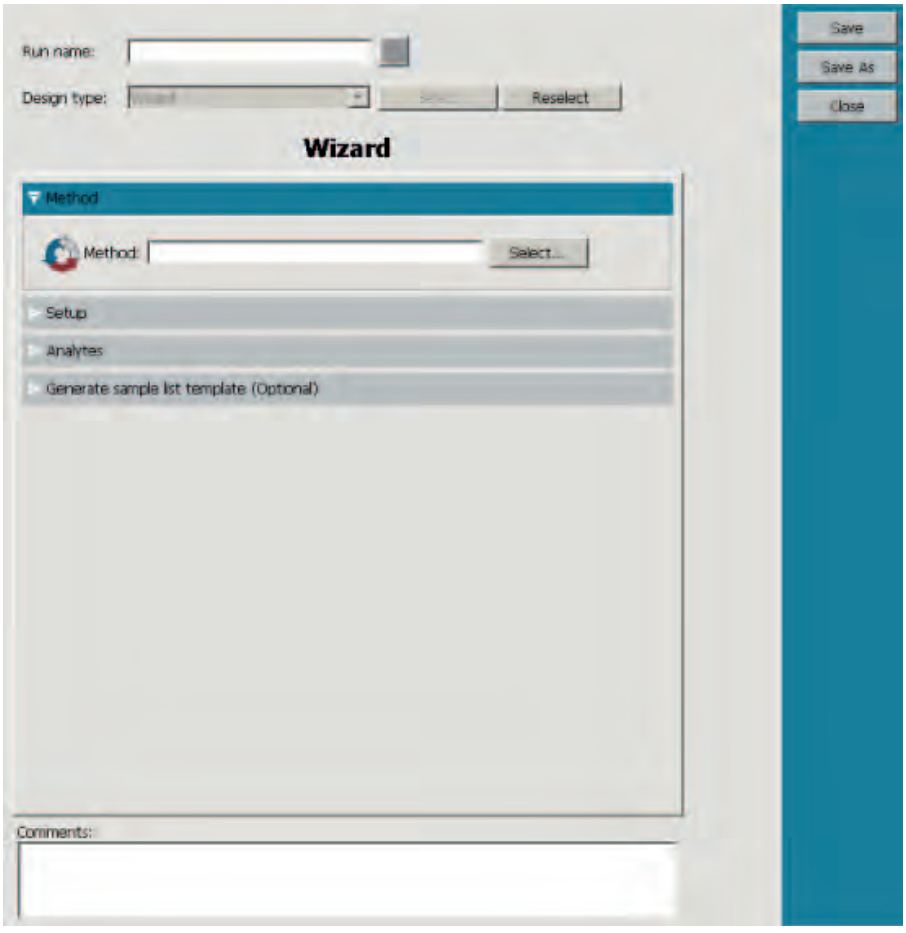
1. Click **Design Run** on the Main menu of Gyrolab Control (refer to Chapter F1.1.2). The **Run** screen appears.



2.
- To create a new Run, click **New** and continue with step step 3.
- To edit an existing Run, browse and select the desired Run and click **Open**. Change desired parameters. For instructions, refer to step step 3 to step 16.

3. Enter a Run name in the **Run Name** field.

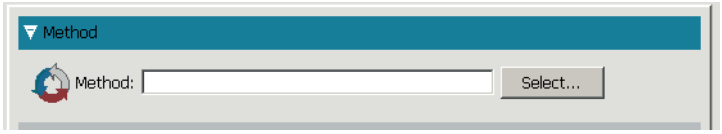
Select Wizard in the **Design Type** list and click **Select**. The **Wizard** panel appears:



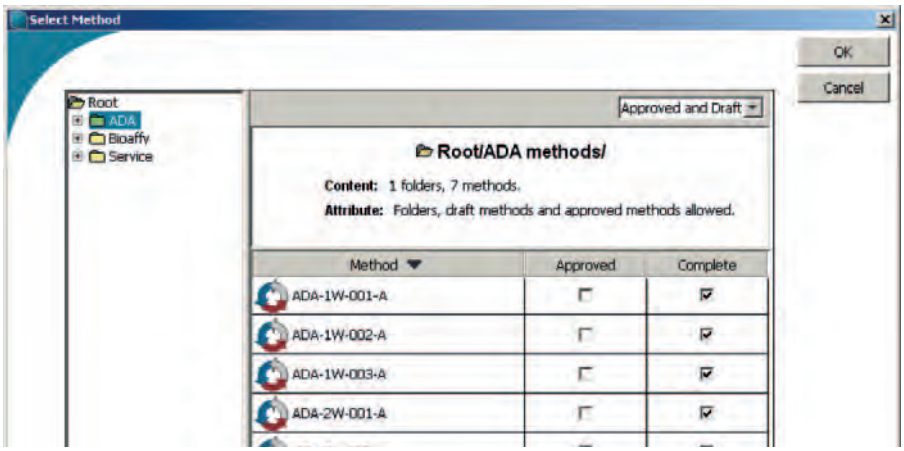
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

4. In the **Method** section, click **Select**.

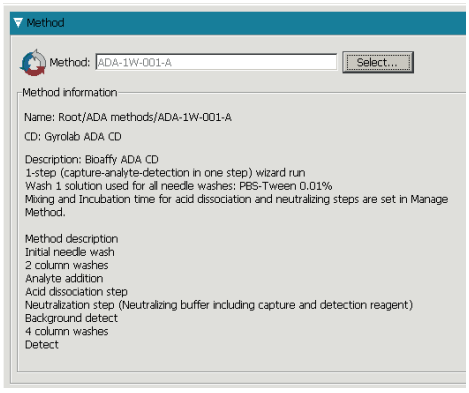


The **Select Method** dialog is opened.



Browse and select desired ADA Method.

Click **OK**. The selected method is added to the run design and method information is displayed


Method
Method: ADA-1W-001-A
Select...
Method information
Name: Root/ADA methods/ADA-1W-001-A
CD: Gyrolab ADA CD
Description: Bioaffy ADA CD
1-step (capture-analyte-detection in one step) wizard run
Wash 1 solution used for all needle washes: PBS-Tween 0.01%
Mixing and Incubation time for acid dissociation and neutralizing steps are set in Manage Method.
Method description
Initial needle wash
2 column washes
Analyte addition
Acid dissociation step
Neutralization step (Neutralizing buffer including capture and detection reagent)
Background detect
4 column washes
Detect

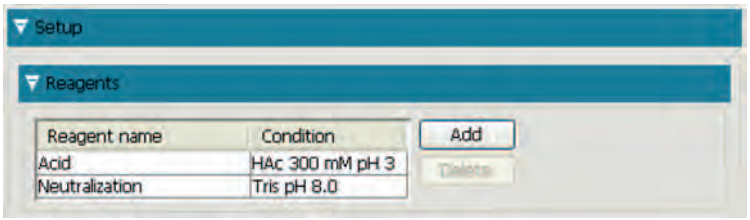
5. Select **Setup**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

6. Select **Reagents**. The number of reagents may differ depending on what assay format and method is used.

NOTE: ***The software will automatically add reagents to the design depending on selected method. The number of reagents can be edited by the user.***



- Enter **Reagent name** for reagents. The **Condition** field is optional and can be used for additional information such as concentration value, matrix or buffer.
- Click **Add** to add more reagents. Add and name one reagent in the software for each different reagent required for the assay.
- Highlight reagent and click **Delete** to remove reagent.

7. Select **Standard series** (This step is optional).

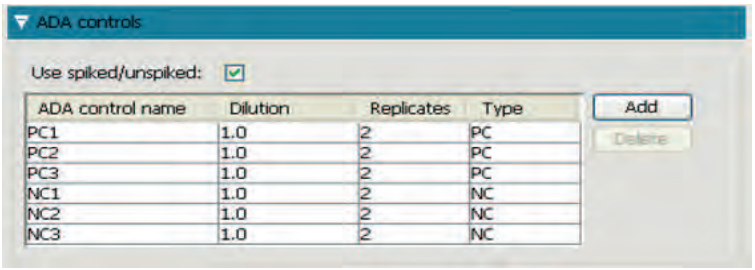
- Standard Series set-up is identical to the workflow used with Gyrolab Bioaffy CDs, refer to Chapter B3.1.2. (Gyrolab xP) or Chapter B3.2.2 (Gyrolab xPlore).

8. Select **Quality Control** (This step is optional).

- Quality Control set-up is identical to the workflow used with Gyrolab Bioaffy CDs, refer to Chapter B3.1.2. (Gyrolab xP) or Chapter B3.2.2 (Gyrolab xPlore).

9. Enter **ADA control name** for ADA controls

- Specify **ADA control name** for ADA controls.
- The **Dilution** field is optional. The dilution value is used for concentration calculations in the evaluation software. The value can be changed during data analysis.
- Set **Type** to PC (positive control) or NC (negative control)
- Mark **Use spiked/unspiked** check box when performing confirmation runs. This automatically doubles the number of ADA controls and sample subgroup for ADA controls is set to "spiked" and "unspiked" respectively within each pair.
- Click **Add** to add more ADA controls.
- Highlight ADA control and click **Delete** to remove ADA control.



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

10. Select **Analytes**.

- Analyte and experiment set-up is identical to the workflow used with Gyrolab Bioaffy CDs, refer to Chapter B3.1.2. (Gyrolab xP) or Chapter B3.2.2 (Gyrolab xPlore) except for the addition of a new sample type: ADA controls.

To set up an Analyte with one Experiment:

- Select **Analyte: Analyte 1**. Enter a name for the Analyte in the **Name** text field.
- Select **Experiment: Experiment 1**. Enter a name for the Experiment in the **Name** text field.
- Select reagent(s) from the drop-down lists. The number of reagent fields is determined by the number of reagent transfer operations in the method and the reagent field names are determined by the reagent transfer operation names in the method. Only reagents specified in step 6 are available in the reagent drop-down lists.

  In the example in step 11, there are two reagent transfer operations in the method and therefore two reagent drop-down lists in the experiment set-up: **Acidic reagent addition** and **Detection reagent mix addition**.
- Select number of Standard series in the **Number of Standard series** list.
  For multi-CD runs:
  - When **Use on all CDs** is ticked, unknown samples will be quantified against Standard series on the same CD. One analysis per CD will be created.
  - If **Use on all CDs** is not ticked, all unknown samples are quantified against the same Standard series.

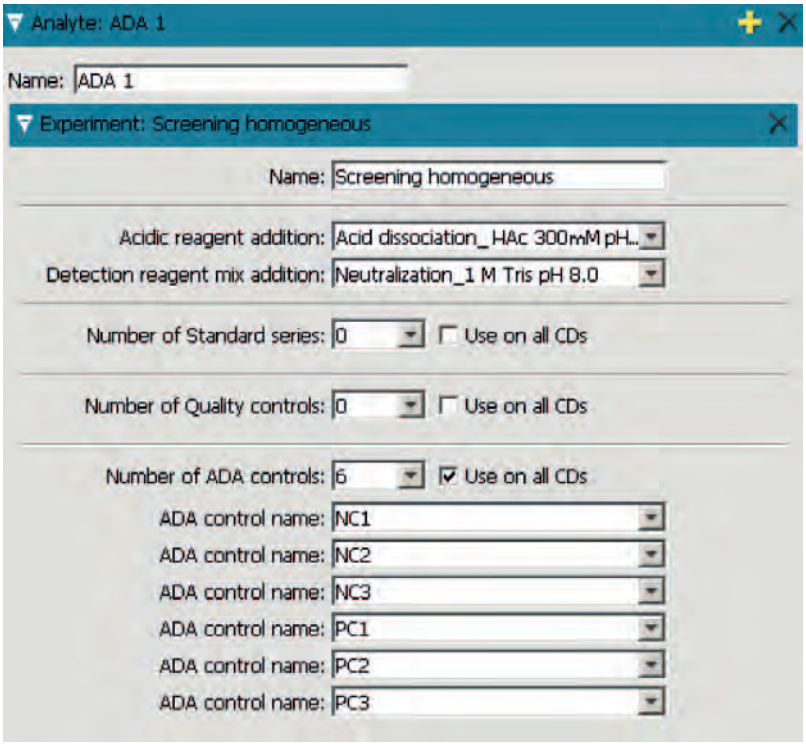
NOTE: ***Instead of Standard series on all CDs, Calibration Controls can be used. Refer to step 7.***

- Select Standard series in the **Standard series name** list. Only Standard series specified in step 7 are available.
- Select number of Quality Controls in the **Number of Quality controls** list.
  For multi-CD runs:
  - If **Use on all CDs** is selected, the Quality Controls samples will be applied on all CDs included in the Run.
  - If **Use on all CDs** is not selected, the Quality Controls samples will be applied on one CD even if the experiment is included on several CDs.
- Select Quality Controls in the **Quality control name** list(s). Only Quality Controls specified in step 8 are available.
- Select number of ADA controls in the **Number of ADA controls** list.
  For multi-CD runs:
  - If **Use on all CDs** is selected, the ADA control samples will be applied on all CDs included in the Run.
  - If **Use on all CDs** is not selected, the ADA control samples will be applied on one CD even if the experiment is included on several CDs.
- Select ADA controls in the **ADA control name** list(s). ADA controls specified in step 9 are available.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

11. An example of an experiment set-up is given below:


Analyte: ADA 1
Name: ADA 1
Experiment: Screening homogeneous
Name: Screening homogeneous
Acidic reagent addition: Acid dissociation_HAc 300mM pH...
Detection reagent mix addition: Neutralization_1 M Tris pH 8.0
Number of Standard series: 0
Use on all CDs
Number of Quality controls: 0
Use on all CDs
Number of ADA controls: 6
Use on all CDs
ADA control name: NC1
ADA control name: NC2
ADA control name: NC3
ADA control name: PC1
ADA control name: PC2
ADA control name: PC3

12. More analytes and experiments can be added:

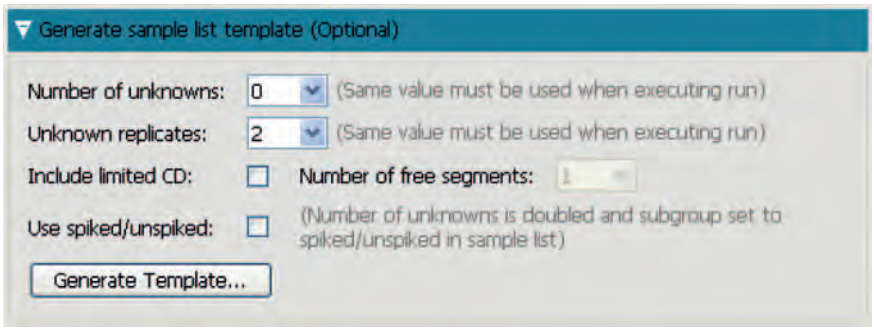
- Add additional Analytes by clicking in the **Analytes** bar.
- Delete Analytes by clicking in the **Analyte:** bar.
- Add additional Experiments to an Analyte by clicking in the **Analyte:** bar.

Delete Experiment by clicking in the **Experiment:** bar.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

13. Select **Generate Sample List template**.


Generate sample list template (Optional)
Number of unknowns:
0
(Same value must be used when executing run)
Unknown replicates:
2
(Same value must be used when executing run)
Include limited CD:
Number of free segments:
1
Use spiked/unspiked:
(Number of unknowns is doubled and subgroup set to spiked/unspiked in sample list)
Generate Template...

- Save the Run.
  - To save a new ADA Run, click **Save**. Browse to select folder and click **Save**.
  - To save an edited ADA Run, click **Save as**. Name the Run, browse to select folder and click **Save**. If **Save** is clicked the information on the original Run will be replaced with the edited information.
  - If any information added to the ADA Run is incomplete or erratic an error message will be presented. The specified issues must be addressed before it is possible to save.
- Specify number of samples to be analyzed ("Unknown samples") in the **Number of unknowns** list.
- Specify number of sample replicates in the **Unknown replicates** list. Highest number of replicates are 8.
- If it is desired to use a CD that previously has been partially used, check **Include limited CD** and define number of available segments in the **Number of free segments** list.
- Mark **Use spiked/unspiked** check box when performing confirmation runs. This will automatically generate a Sample List where the number of unknown samples are doubled and sample subgroup for unknown samples is set to "spiked" and "unspiked" respectively within each pair.
- Click **Generate template**.
- Browse to select Sample List location and click **Save**.

A Sample List is generated. The Sample List contains all necessary sample information defined in the run design. It also holds a suggestion for sample placement within the microplate.

NOTE: ***The procedure described in this step is the most convenient way to generate a Sample List. Sample Lists can created manually and automatically generated lists can be edited prior to run start, refer to Chapter B3.1.3. However, Gyros recommends using the automatically generated Sample Lists as this will reduce the risk or errors.***

14. Comments for the Run can be made in the **Comments** window, for example what type of assays the run is intended for.

15. Save the Run.

16. Click **Close** to finish the Design Run procedure.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

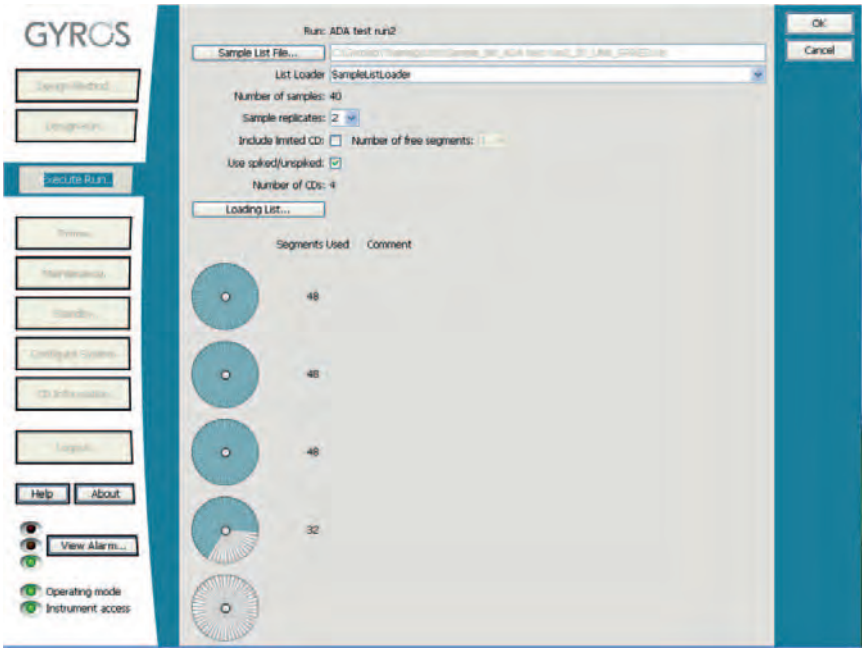
D2.3 Prepare Run

Sample preparation is carried out as described in Gyrolab ADA assay protocol. The protocol is included in the purchase of Gyrolab ADA Software. This chapter describes run preparation for an ADA Run.

Step	Action
1.	Click **Execute Run** in the Main menu of Gyrolab Control (refer to Chapter F1.1.2).
2.	Browse and select desired **Run** from the list and click **OK**.
	Runs that are not complete and thus not ready to execute, are marked with a zigzag line. More information is needed before the Run can be executed.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
3.	The Execute Run screen is opened.



- To load a Sample List, click **Sample List File**, browse and select desired list.
- **List Loader** file sets rules for how to import Sample list. Choose the **SampleList-Loader** option in the drop down menu.
- Number of Unknown samples will be displayed in the **Number of samples** field when the desired Sample List is loaded.
- The number of Unknown sample replicates was defined during run design (Chapter D2.2) and is displayed in the **Sample replicates** list. Sample replicate number can be changed compared what was defined during the run design.
- **Include limited CD** box is ticked if a partially used (limited) CD was included when the run was designed (Chapter D2.2). It will always be the first CD in the Run that is partially used. It is possible to remove limited CD or change number of available Mixing CD structures. The Gyrolab Mixing CD has 48 structures.
- Mark **Use spiked/unspiked** check box if this option was used during Run set-up (Chapter D2.2).

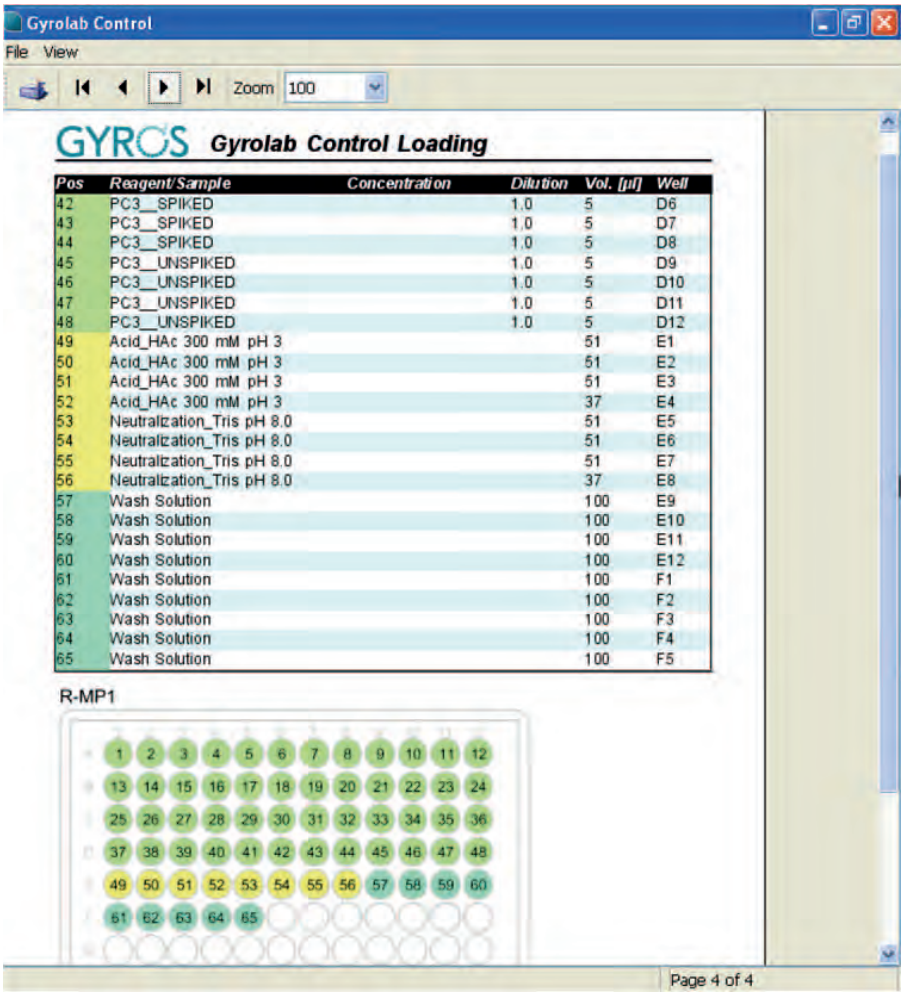
The CD structure consumption is calculated based on number of samples and replicates. For all samples, position on the CD(s) is automatically randomized and distributed by the software. For multiple-CD runs: If Calibration Controls are used, these are placed on each CD that does not have a corresponding Standard series.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

4. Click **Loading List**.

Gyrolab Control Loading screen is opened.


Gyrolab Control
File View
Zoom 100
GYROS Gyrolab Control Loading
Pos Reagent/Sample Concentration Dilution Vol. [µl] Well
42 PC3__SPIKED 1.0 5 D6
43 PC3__SPIKED 1.0 5 D7
44 PC3__SPIKED 1.0 5 D8
45 PC3__UNSPIKED 1.0 5 D9
46 PC3__UNSPIKED 1.0 5 D10
47 PC3__UNSPIKED 1.0 5 D11
48 PC3__UNSPIKED 1.0 5 D12
49 Acid_HAc 300 mM pH 3 51 E1
50 Acid_HAc 300 mM pH 3 51 E2
51 Acid_HAc 300 mM pH 3 51 E3
52 Acid_HAc 300 mM pH 3 37 E4
53 Neutralization_Tris pH 8.0 51 E5
54 Neutralization_Tris pH 8.0 51 E6
55 Neutralization_Tris pH 8.0 51 E7
56 Neutralization_Tris pH 8.0 37 E8
57 Wash Solution 100 E9
58 Wash Solution 100 E10
59 Wash Solution 100 E11
60 Wash Solution 100 E12
61 Wash Solution 100 F1
62 Wash Solution 100 F2
63 Wash Solution 100 F3
64 Wash Solution 100 F4
65 Wash Solution 100 F5
R-MP1
Page 4 of 4

- **Gyrolab Control Loading** holds microplate loading information and is used when preparing microplates for a run. Name, concentration, volume, microplate and well position is included for all sample types. An overview of microplates with indication of used wells is also provided.
- Click **Printer** button to print the **Gyrolab Control Loading**.

TIP: ***Select* File: Export *to export the Loading list in PDF or text format. This is useful when printing from another computer is required.***

Close **Gyrolab Control Loading**.

5. Click **OK**.

A screen with two tabs, **Targets** and **Reports**, is opened. Refer to step 7 and step 8 in Chapter B3.1.4 for information on target and report settings.

6. Click **OK** and prepare samples and reagents as described in the Assay protocol for ADA.

7. Load instrument and start the Run as described in Chapter B5.

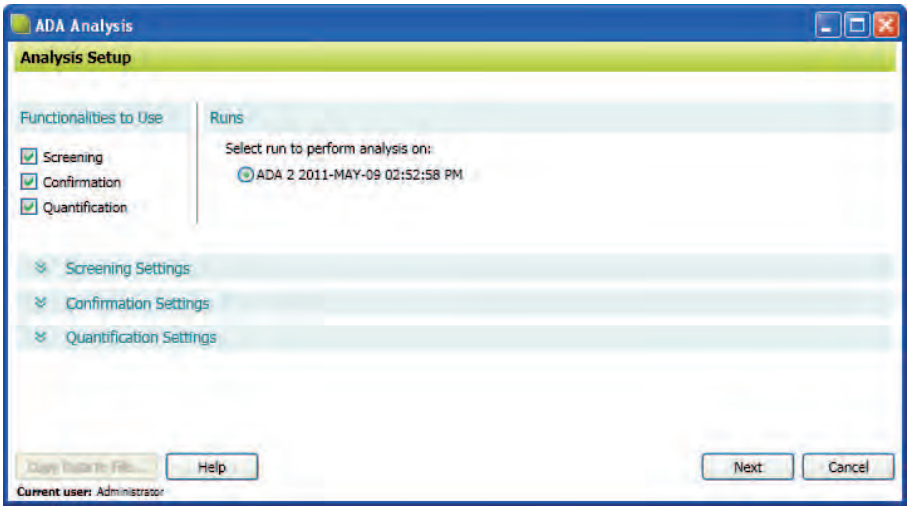
8. When the Run is completed, unload instrument and finish Run as described in Chapter B6.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D2.4 Data evaluation

This chapter describes how to evaluate run data from an ADA Run. The data analysis is performed in Gyrolab Evaluator using the software module Gyrolab ADA Software.

Step	Action
1.	In Gyrolab Evaluator Project view (Chapter C3.1), select an ADA run and click the **ADA Analysis** button .
2.	The **ADA Analysis** window opens.



- Select what analysis **Functionalities to use** by marking check boxes as appropriate.
- In the **Runs** section, select desired Run for analysis.
- Analysis Settings for each functionality are set in the **Screening Settings**, **Confirmation Settings** and the **Quantification Settings** sections. Click on the section to expand it.
  - For **Screening** analysis, continue to Chapter D2.4.1.
    Screening assays are performed to screen for ADA positive samples. The Screening functionality is used during assay development and validation and for routine analysis.
  - For **Confirmation** analysis, continue to Chapter D2.4.2.
    Confirmation assays are performed to investigate whether positive samples from screening assays are true positives. Confirmation functionality is used during assay development and validation and for routine analysis.
  - For **Quantification** analysis, continue to Chapter D2.4.3.
    The Quantification functionality is used during ADA assay development and validation. It offers the same functionality as the Quantification module used when analyzing results from immunoassays performed in Gyrolab Bioaffy CDs (described in Chapter C4.1).

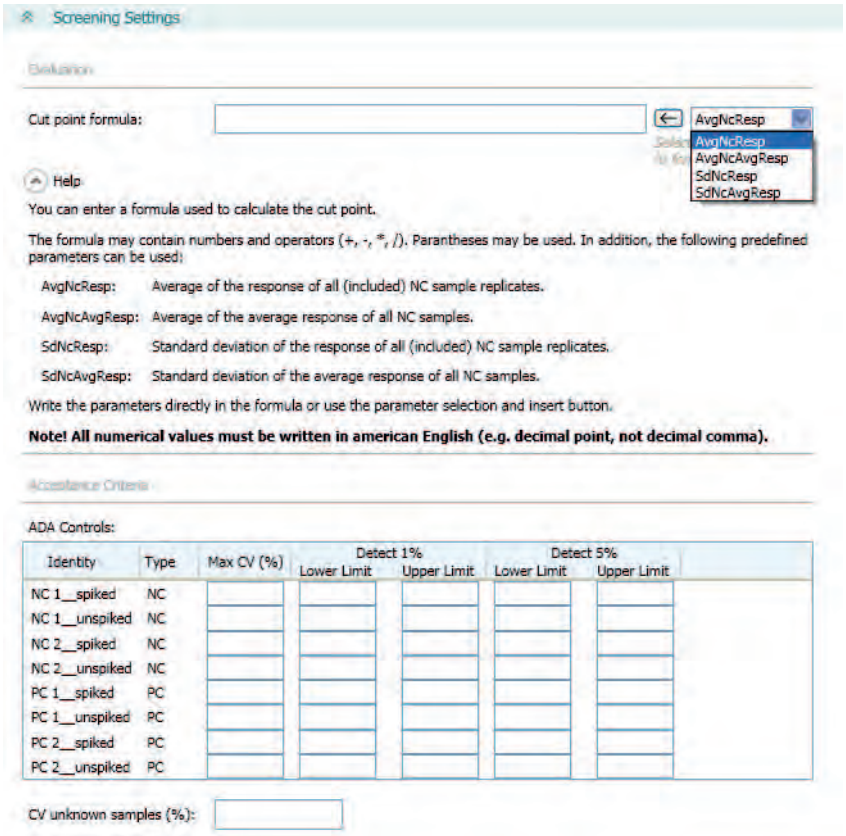
D2.4.1 Screening

During ADA analysis clinical samples are screened for ADA positives in a **Screening** assay. The Screening functionality is also used during assay development and validation.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

1. In the ADA Analysis window (Chapter D2.4), click on **Screening Settings**. The Screening Settings panel opens.


Screening Settings
Evaluation
Cut point formula:
AvgNcResp
AvgNcResp
AvgNcAvgResp
SdNcResp
SdNcAvgResp
Help
You can enter a formula used to calculate the cut point.
The formula may contain numbers and operators (+, -, *, /). Parantheses may be used. In addition, the following predefined parameters can be used:
AvgNcResp: Average of the response of all (included) NC sample replicates.
AvgNcAvgResp: Average of the average response of all NC samples.
SdNcResp: Standard deviation of the response of all (included) NC sample replicates.
SdNcAvgResp: Standard deviation of the average response of all NC samples.
Write the parameters directly in the formula or use the parameter selection and insert button.
Note! All numerical values must be written in american English (e.g. decimal point, not decimal comma).
Acceptance Criteria
ADA Controls:
Identity
Type
Max CV (%)
Detect 1%
Lower Limit
Upper Limit
Detect 5%
Lower Limit
Upper Limit
NC 1__spiked NC
NC 1__unspiked NC
NC 2__spiked NC
NC 2__unspiked NC
PC 1__spiked PC
PC 1__unspiked PC
PC 2__spiked PC
PC 2__unspiked PC
CV unknown samples (%):

- In the **Evaluation** section, enter cut point formula in the **Cut point formula** field. Enter numbers, operators and/or parameters or build your cut point formula using the parameters in the drop-down list. A help section is available with explanations on available functions.

  For multi-CD runs: Averages of ADA control response values and standard deviations can be included in the cut point formula. If ADA controls are applied to all CDs in the run (check box **Use on all CDs** is ticked (Chapter D2.2)), the average ADA control responses and standard deviations will be calculated for each CD individually and resulting cut point used to evaluate samples on that specific CD. If ADA Controls are applied only to one CD in the run, the average of ADA control results for this CD will be used to calculate a cut point and the same cut point will be used to evaluate all samples on all CDs.

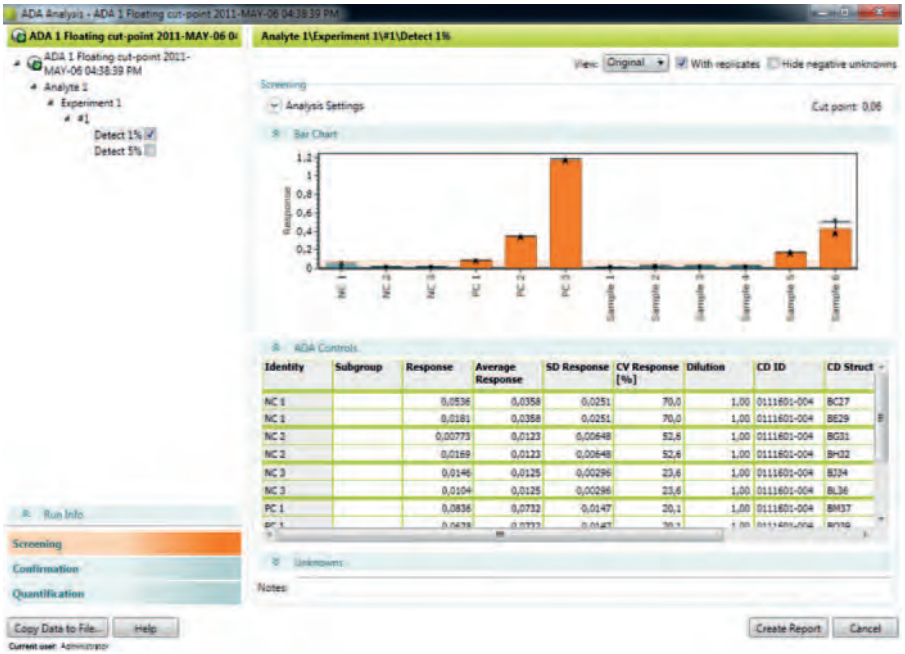
  What screening cut point formula to apply for the assay is determined during the assay validation phase. For more information on cut point determination, refer to Gyrolab ADA assay protocol.

NOTE: ***Gyros recommends using floating cut point and to include ADA controls on all CDs in a run.***

- In the **Acceptance Criteria** section, add acceptance criteria for ADA controls for precision in the fields **Max CV (%)** and for response values in fields **Lower Limit** and **Upper Limit.** Add acceptance criteria for Unknown samples in the field **CV unknown samples (%)**. Values for upper and lower limit can be set for each detect operation in the method.
- Click **Next**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
2.	Click **Screening** in the lower left corner. The Screening window opens.



The left panel of the Screening window displays available experiments in the Run and Run information, refer to Chapter C4.1.

The right panel of the Screening window displays collapsable/expandable views for:

- **Bar Chart:** Visualizes average response results for ADA controls and unknown samples compared to the screening cut point. Standard deviations are indicated with error bars. Samples above cut point are indicated with orange bar color. Samples below cut point are indicated with blue bar color.
- **ADA controls:** Data table with analysis results for ADA controls. ADA controls with results that fall outside of acceptance criteria (as set up in step 1) are highlighted. Negative controls with response above screening cut point and positive controls with response below screening cut point are highlighted. Refer to Chapter D2.4.1.1 for detailed information on column data.
- **Unknowns:** Data table with analysis results for unknown samples. Samples with results that fall outside of acceptance criteria set in step 1 are highlighted. Refer to Chapter D2.4.2.1 for detailed information on column data.

3. Click **Analysis settings** to change settings for the Screening functionality.

4. To simplify bar chart view and facilitate data evaluation it is possible to hide unknown samples with response values below the cut point.
   - Mark check box **Hide negative unknowns**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

5. General commands for data tables:

- In the **View** list, select display option for data tables:
  - **Original**: A selected number of data columns (default)
  - **Extended**: All available data columns
- If the **With replicates** box is ticked (default) all replicates for samples are shown in the table and in the bar chart. Untick the box to display average values for samples.
- It is possible to include or exclude data points:
  - To exclude a data point, right-click on the sample and select **Exclude**. To perform this With replicates must be ticked. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
  - To include an excluded sample, right-click on the sample and select **Include**. To perform this With replicates box must be ticked. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
- It is possible to edit **Dilution** values. If required by Project settings, the reason for editing must be specified. The change description is included in the Audit Trail.
- It is possible to add **Notes** for individual samples in the right-most column if With replicates box is ticked and View list is set to Extended.

NOTE: ***The number and titles of columns may differ depending on the Run and if replicates are shown or not.***

6. It is possible to add general experiment comments in the **Notes** text box located at bottom of the right panel.

7. To export data or generate analysis report, continue to Chapter D2.4.4.

D2.4.1.1 Data table descriptions - Screening

Columns that are displayed in the **Screening** view will be included in reports generated.

If Original view is selected (refer to Chapter D2.4.1, step 7) only columns indicated with a Yes below will be displayed. If Extended view is selected all available columns are shown.

Column heading	Original view	Description
Identity	Yes	Sample identity
Subgroup	Yes	Sample subgroup, as set during Run set-up, refer to Chapter D2.2.2.
Response	Yes	Integrated volume of the fluorescent binding surface of a reaction in a microstructure.
Average Response	Yes	Average of response values for replicates of a sample, sample group or sample subgroup.
SD Response	Yes	The standard deviation of responses of sample replicates.
CV Response (%)	Yes	Coefficient of variation of response of replicates of a sample.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

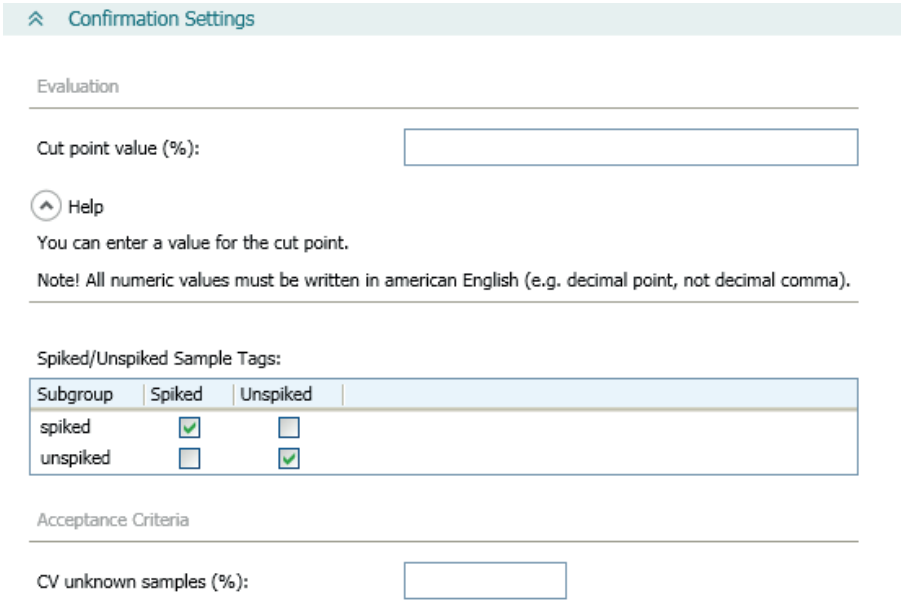
Column heading	Original view	Description
Dilution	Yes	Dilution factor for Unknown samples is entered in the Sample List. For ADA control samples the dilution factor is entered entered during Run set-up, refer to Chapter D2.2. If no Dilution Factor value has been assigned a factor of 1 will automatically be used.
CD ID	Yes	Identity of Gyrolab CD microlaboratory used to process the samples.
CD Structure	Yes	Identity of structure on Gyrolab CD microlaboratory where the sample was processed.
Average Cut Point	Yes	Describes whether average sample response for replicates of a sample, sample group or sample subgroup are above or below cut point. Negative or positive.
Cut Point	Yes	Describes whether sample response is above or below cut point. Negative or positive.
Log of Response	No	The logarithm of Response value.
Log of Average Response	No	The logarithm of Average Response value.
MP Identity	No	Identity of the microplate where the sample was placed.
MP Well	No	Well position on the microplate where the sample or standard was placed.
Detect Result	No	• OK: The results are approved • Not OK: The results are not approved. The fluorescence signal is of poor quality which may be caused by inadequate PMT setting (detector is saturated) or errors in sample preparation.
Sample Type	No	For ADA controls: Negative control or Positive control. For unknown sample: Unknown
Needle ID	No	The needle used to transfer the sample from the MP to the CD structure
Notes	No	It is possible to add comments to individual samples.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D2.4.2 Confirmation

Confirmation assays are performed to investigate whether positive samples from screening assays are true positives.

Step	Action
1.	In the ADA Analysis window (Chapter D2.4), click on **Confirmation Settings**. The Confirmation Settings panel opens.



- In the **Evaluation** section, enter cut point value in the **Cut point value** field. A help section is available with explanations on how to enter numerical values.

  What confirmation cut point to apply for the assay is determined during the assay validation phase. For more information on cut point determination, refer to Gyrolab ADA assay protocol.

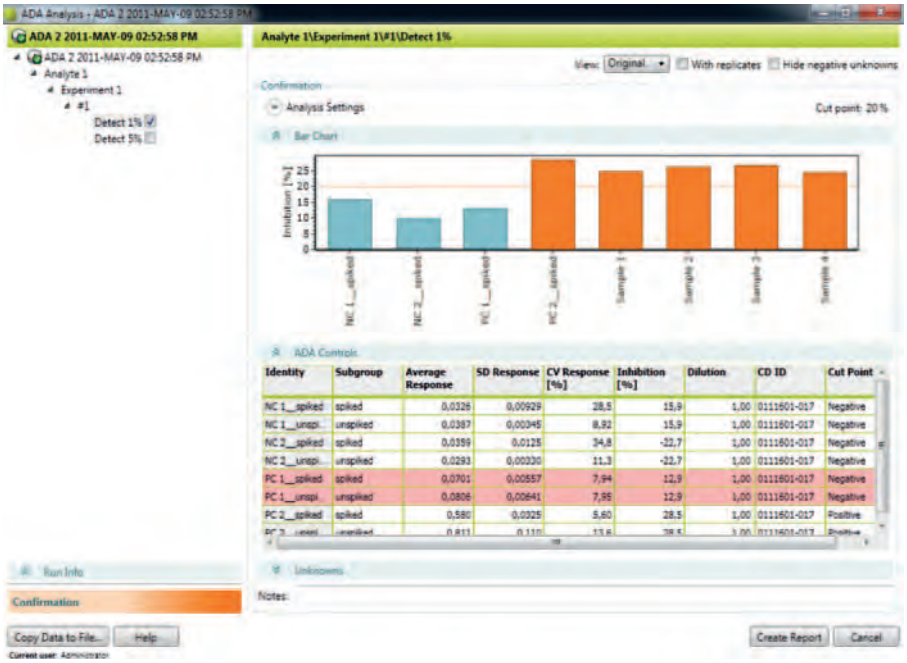
NOTE: ***The confirmation functionality calculates the "percent inhibition" for samples. This serves as a base to determine the confirmation cut point.***

- In the **Evaluation** section, mark check boxes to indicate what sample subgroups that have been spiked and which are unspiked.
- In the **Acceptance Criteria** section, add acceptance criteria for Unknown samples in the field **CV unknown samples (%)**.
- Click **Next**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

2. Click **Confirmation** in the lower left corner. The Confirmation window opens.



The left panel of the Confirmation window displays available experiments in the Run and Run information, refer to Chapter C4.1.

The right panel of the Confirmation window displays collapsable/expandable views for:

- **Bar Chart:** Visualizes inhibition value for ADA controls and unknown samples compared to the confirmation cut point. Standard deviations are indicated with error bars. Values above cut point are indicated with orange bar color. Values below cut point are indicated with blue bar color. A true positive should be above confirmation cut point.
- **ADA controls:** Data table with analysis results for ADA controls. ADA control with results that fall outside of acceptance criteria set in step 1 are highlighted. Negative controls with response above confirmation cut point and positive controls with response below confirmation cut point are highlighted. Refer to Chapter D2.4.2.1 for detailed information on column data.
- **Unknowns**: Data table with analysis results for unknown samples. Samples with results that fall outside of acceptance criteria set in step 1 are highlighted. Refer to Chapter D2.4.2.1 for detailed information on column data.

3. Click **Analysis settings** to change settings for the confirmation view.

4. To simplify bar chart view and facilitate data evaluation it is possible to hide unknown samples with response values below the cut point.

- Mark check box **Hide negative unknowns**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

5. General commands for data tables:

- In the **View** list, select display option for data tables:
  - **Original**: A selected number of data columns (default)
  - **Extended**: All available data column
- If the **With replicates** box is ticked (default) all replicates for samples are shown. Untick the box to display average values for samples.
- It is possible to include or exclude data points:
  - To exclude a data point, right-click on the sample and select **Exclude**. To perform this With replicates must be ticked. If required by Project settings, the reason for exclusion must be specified. The change description is included in the Audit Trail.
  - To include an excluded sample, right-click on the sample and select **Include**. To perform this With replicates box must be ticked. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
- It is possible to edit **Dilution** values. If required by Project settings, the reason for editing must be specified. The change description is included in the Audit Trail.
- It is possible to add **Notes** for individual samples in the right-most column if With replicates box is ticked and View list is set to Extended.

NOTE: ***The number and titles of columns may differ depending on the Run and if replicates are shown or not.***

6. Optional: Add general experiment comments in the **Notes** text box located at bottom of the right panel.

7. To export data or generate analysis report, continue to Chapter D2.4.4.

D2.4.2.1 Data table descriptions - Confirmation

Columns that are displayed in the **Confirmation** view will be included in reports generated.

If Original view is selected only columns indicated with a Yes below will be displayed. If Extended view is selected all available columns are shown.

Column heading	Original view	Description
Identity	Yes	Sample identity
Subgroup	Yes	Sample subgroup, as set during Run set-up, refer to Chapter D2.2.2.
Response	Yes	Integrated volume of the fluorescent binding surface of a reaction in a microstructure.
Average Response	Yes	Average of response values for replicates of a sample, sample group or sample subgroup.
SD Response	Yes	The standard deviation of responses of sample replicates.
CV Response (%)	Yes	Coefficient of variation of response of replicates of a sample.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

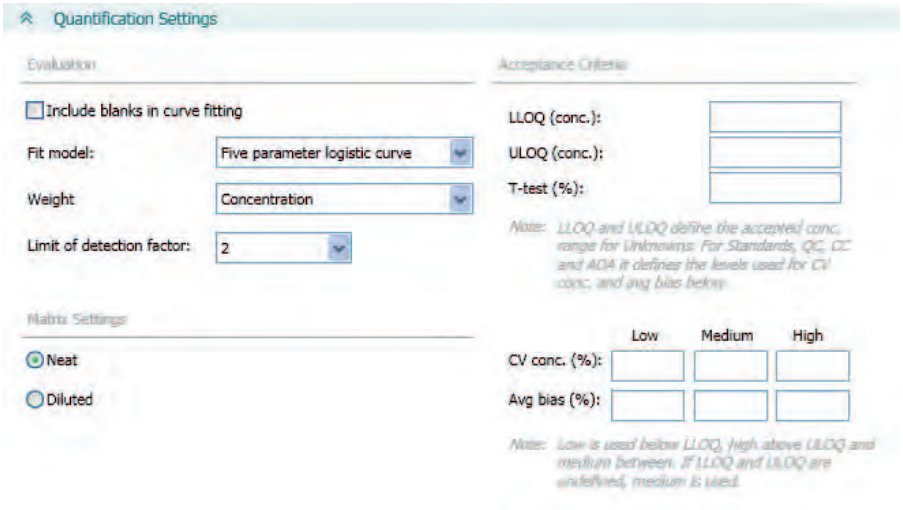
Column heading	Original view	Description
Inhibition (%)	Yes	Inhibition is calculated as: %Inhibition = 1-(response for spiked samples)/(response for unspiked samples)
Dilution	Yes	Dilution factor for Unknown samples is entered in the Sample List. For ADA control samples the dilution factor is entered during Run set-up, refer to Chapter D2.2. If no Dilution Factor value has been assigned a factor of 1 will automatically be used.
CD ID	Yes	Identity of Gyrolab CD microlaboratory used to process the samples.
CD Structure	Yes	Identity of structure on Gyrolab CD microlaboratory where the sample was processed.
Cut Point	Yes	Describes whether sample response is above or below cut point. Negative or positive.
Log of Response	No	The logarithm of Response value.
Log of Average Response	No	The logarithm of Average Response value.
MP Identity	No	Identity of the microplate where the sample was placed.
MP Well	No	Well position on the microplate where the sample or standard was placed.
Detect Result	No	• OK: The results are approved • Not OK: The results are not approved. The fluorescence signal is of poor quality which may be caused by inadequate PMT setting (detector is saturated) or errors in sample preparation.
Sample Type	No	For ADA controls: Negative control or Positive control. For unknown sample: Unknown
Needle ID	No	The needle used to transfer the sample from the MP to the CD structure
Notes	No	It is possible to add comments to individual samples.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D2.4.3 Quantification

The **Quantification** functionality is used during ADA assay development and validation. It offers the same functionality as the Quantification module used when analyzing results from immunoassays performed in Gyrolab Bioaffy CDs (Chapter C4.1),

Step	Action
1.	In the ADA Analysis window (Chapter D2.4), Click on **Quantification Settings**. The Quantification Settings panel opens.


Quantification Settings
Evaluation
Include blanks in curve fitting
Fit model:
Five parameter logistic curve
Weight
Concentration
Limit of detection factor:
2
Matrix Settings
Neat
Diluted
Acceptance Criteria
LLOQ (conc.):
ULOQ (conc.):
T-test (%):
Note: LLOQ and ULOQ define the accepted conc. range for Unknowns. For Standards, QC, CC and ADA it defines the levels used for CV conc. and avg bias below.
Low
Medium
High
CV conc. (%):
Avg bias (%):
Note: Low is used below LLOQ, high above ULOQ and medium between. If LLOQ and ULOQ are undefined, medium is used.

- Set or edit analysis setting in the **Evaluation**, **Matrix Settings** and **Acceptance Criteria**, refer to Chapter C4.4 for more information.
- Click **Next**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

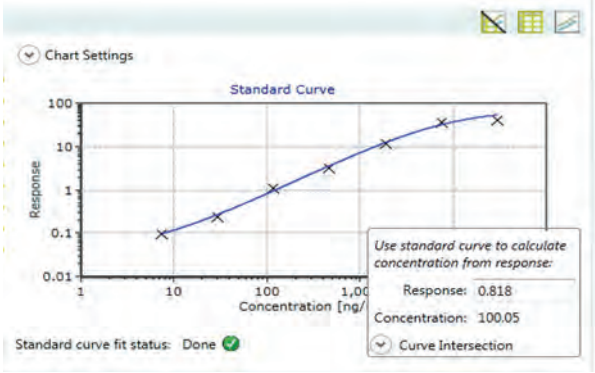
2. Click **Quantification** in the lower left corner. The Quantification window opens.

The left panel of the Quantification window displays available experiments in the run and Run information, refer to Chapter C4.1.

The right panel of the Quantification window displays collapsable/expandable views for:

- **Standards**, described in Chapter C4.1
- **Quality Controls**, described in Chapter C4.1
- **Calibration Controls**, described in Chapter C4.1
- **ADA controls**, data table with analysis results for ADA controls.
- **Unknowns**, described in Chapter C4.1

3. Click **Curve Intersection** and enter a response value to get a concentration value for where response intersects with standard curve.



4. View options, chart settings, chart zooming, inclusion/exclusion of data point, notes and analysis settings are explained in detail in Chapter C4.1. and descriptions for data tables are found in Chapter C4.3.

5. To export data or generate analysis report, continue to Chapter D2.4.4.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D2.4.4 Data export and report generation

Step	Action
1.	Optional: To export data to tab separated text format (.txt) or to Excel XML spreadsheet format (.xls), click **Copy Data To File** button, browse for desired location and click **Save**. This functionality is useful when further data analysis e.g cut point determination calculations are needed. ***NOTE:*** ***No traceability of results is achieved using Copy Data To File. A copy of a Result file is created but this can be done for example before an analysis is saved and it is NOT logged in the Audit Trail. To fulfil the requirements of 21 CFR part 11 data must be exported from a saved Project, refer to Chapter C3.5***
2.	Click **Create Report** to save analysis. All results from chosen included experiments and analysis functionalities (Screening, Confirmation, Quantification) will be included in the report.
3.	Set **Analysis Name** and click **OK**.

D2.5 Installation of Gyrolab ADA Software

The Gyrolab ADA Software module is available for Gyrolab Control version 5.4 or higher and Gyrolab Evaluator version 3.3 and is activated by the user with a licence key. Licences are instrument specific. Contact Gyros to purchase Gyrolab ADA Software and receive a licence.

To register the licence: Save the licence file to the hard drive of the instrument computer at the destination: `C:\ProgramData\Gyros\Licenses`.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

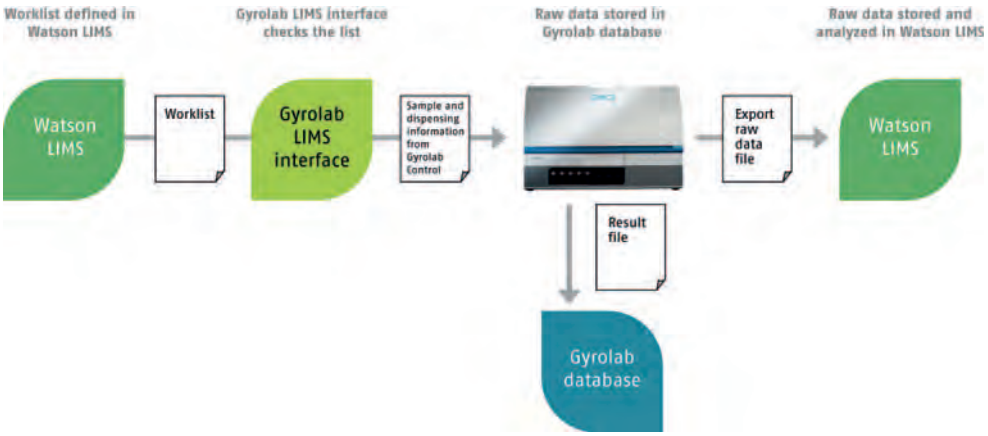
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D3 Gyrolab LIMS Interface

Visit www.gyros.com for the latest updates on available software modules.

D3.1 Introduction to Gyrolab LIMS Interface workflow

Gyrolab LIMS Interface is a software add-on module for Gyrolab Control version 5.2 or higher and is compatible with the generic raw data file for Watson LIMS 6.4. The software module is designed to support users that carry out experiment set-up and data analysis within a LIMS system.


Worklist defined in Watson LIMS
Gyrolab LIMS interface checks the list
Raw data stored in Gyrolab database
Raw data stored and analyzed in Watson LIMS
Watson LIMS
Worklist
Gyrolab LIMS interface
Sample and dispensing information from Gyrolab Control
Export raw data file
Watson LIMS
Result file
Gyrolab database

The LIMS workflow (Chapter D3) differs from the standard Wizard run design (Chapter B). Sample preparations, run start and run finish procedures are the same for both workflows and described in Chapter B4 – Chapter B6. Hence, only LIMS module specific parts of performing a run is described in this section.

Step	Wizard Run	LIMS Run
Create or Edit Run	• Select Wizard Run design type • Enter experiment parameters • Save Wizard Run Chapter B3.1.2 (Gyrolab xP) Chapter B3.2.2 (Gyrolab xPlore)	• Select LIMS Run design type • Enter experiment parameters • Set result file output format • Save LIMS Run Chapter D3.2
Sample List or Worklist(s)	Sample List generated by: • Gyrolab Control or • manual editing (.xls) Chapter B3.1.3 (Gyrolab xP) Chapter B3.2.3 (Gyrolab xPlore)	Worklist(s) generated by: • LIMS Chapter D3.3

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

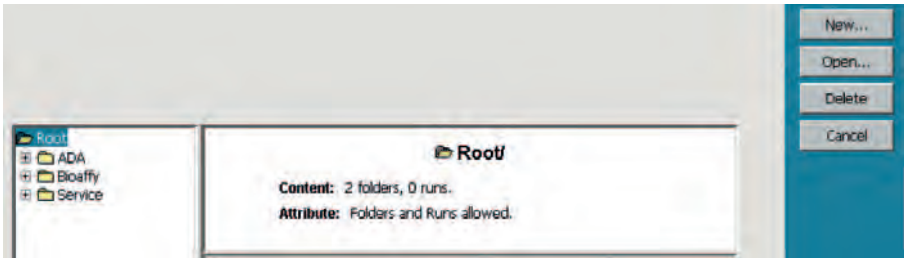
Step	Wizard Run	LIMS Run
Prepare Run	• Select Wizard Run • Select Sample List • Enter experimental parameters • Set name and folder for result files • Set name and folder for reports • Generate Loading List Chapter B3.1.4 (Gyrolab xP) Chapter B3.2.4 (Gyrolab xPlore)	• Select LIMS Run • Select Worklist(s) • Enter experimental parameters • Set name and folder for result files • Set name and folder for reports • Generate Loading List Chapter D3.4

D3.2 Create or edit a LIMS Run

There are three options available when setting up a new run:

- Create a new Run, proceed with D3.2
- Edit an existing Run (use when similar but not identical experiment design is wanted), proceed with D3.2
- Use an existing Run (use when identical experiment design is wanted), go to D3.4.

Step	Action
1.	Click **Design Run** on the Main menu. The **Run** screen appears.



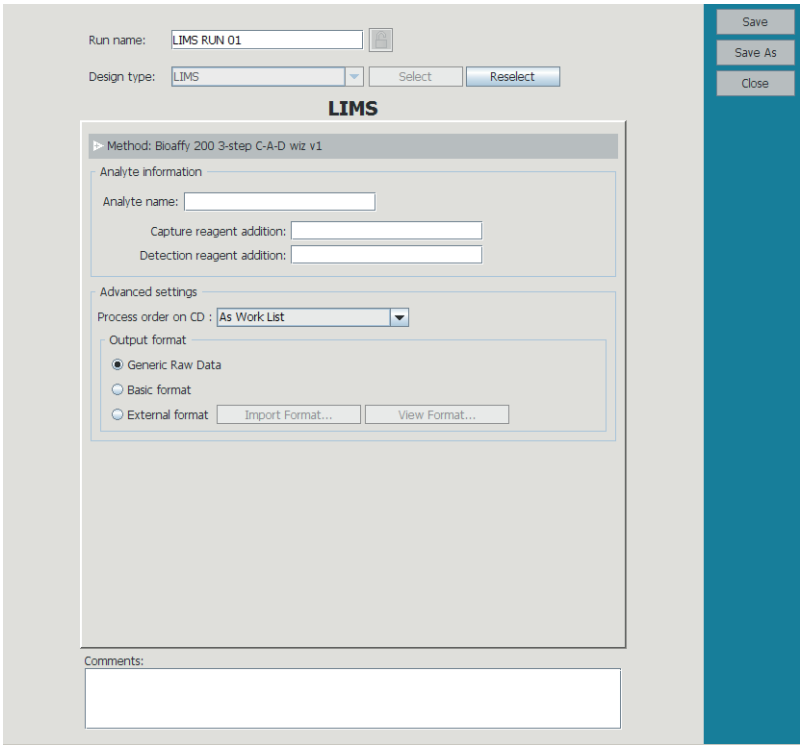
2.
- To create a new Run, click **New**. Enter a Run name in the **Run Name** field.
- To edit an existing Run, browse and select the desired Run and click **Open**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

3.

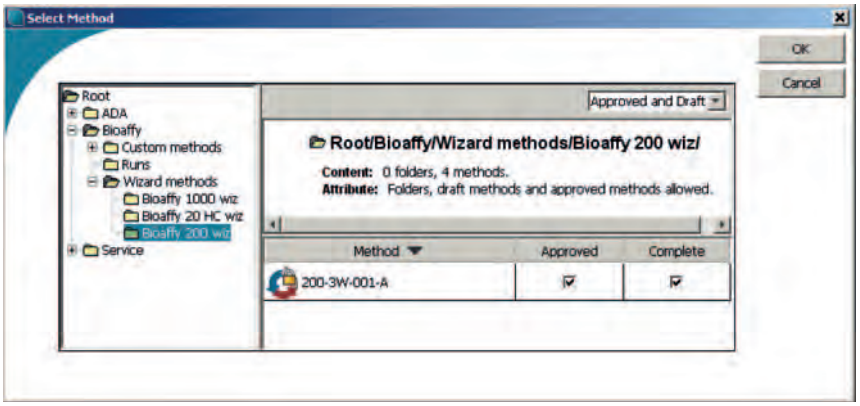
- Select **LIMS** in the **Design Type** list and click **Select**. The **LIMS** panel appears:



- To change design type. highlight the design type in the **Design type** list and click **Reselect**.
- Comments for the Run can be made in the **Comments** window, for example what type of assays the run is intended for.

4. Select **Method** and click **Select**.

The **Select Method** dialog opens.

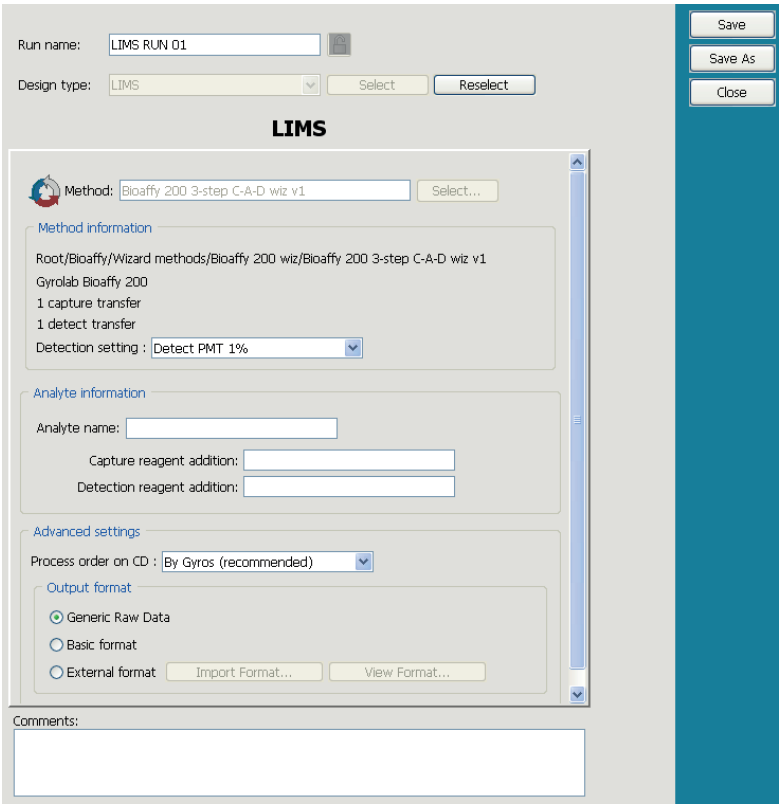


Browse and select desired Method in the folder structure. Click **OK**.

NOTE: Use the Method that was used during assay development.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
5.	It is now possible to add and edit **Method information**, **Analyte information** and **Advanced settings**.



6.	In the **Method information** panel, select a detection setting from the **Detection setting** list. Result files will only contain data for the selected detection level.
7.	In **Analyte information** panel set: • **Analyte name** • Capture reagent name(s) (**Capture reagent addition**) • Detection reagent name(s) (**Detection reagent addition**) ***NOTE:*** ***The number of capturing and detecting reagents displayed may differ depending on the Method (1-step, 2-step, 3-step or 4-step).***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

8. In **Advanced settings** panel select:

- **Process order on CD**. The selection defines how samples are distributed on CDs. Options available:
  - **As Work List.** Select this option to place samples in the order defined in the worklist generated in the LIMS.
  - **By Gyros**. Gyrolab Control distributes samples on CDs to achieve optimal distribution of sample replicates.
- **Output format**. Options available:
  - **Generic Raw Data** (default). All work list information and results are exported in tab delimited text format (.txt) compatible with Watson LIMS.
  - **Basic format**. Sample ID and results are exported in tab delimited text format (.txt).
  - **External format**. Click **Import Format** button to browse and select desired format. Click **View Format** button to view selected format. External format is used when a customized output format is required, contact Gyros for more information.

9.

- To save a new LIMS Run, click **Save**. In the **Save as** window, browse to select folder and click **Save**.
- To save an edited LIMS Run, click **Save as**. Name the Run, browse to select folder and click **Save**. If **Save** is clicked the information on the original Run will be replaced with the edited information.

NOTE: ***If any information added to the LIMS run is incomplete or erratic an error message will be presented. The specified issues must be addressed before it is possible to save.***

10. Click **Close** to finish the Design Run procedure.

D3.3 LIMS worklist generation

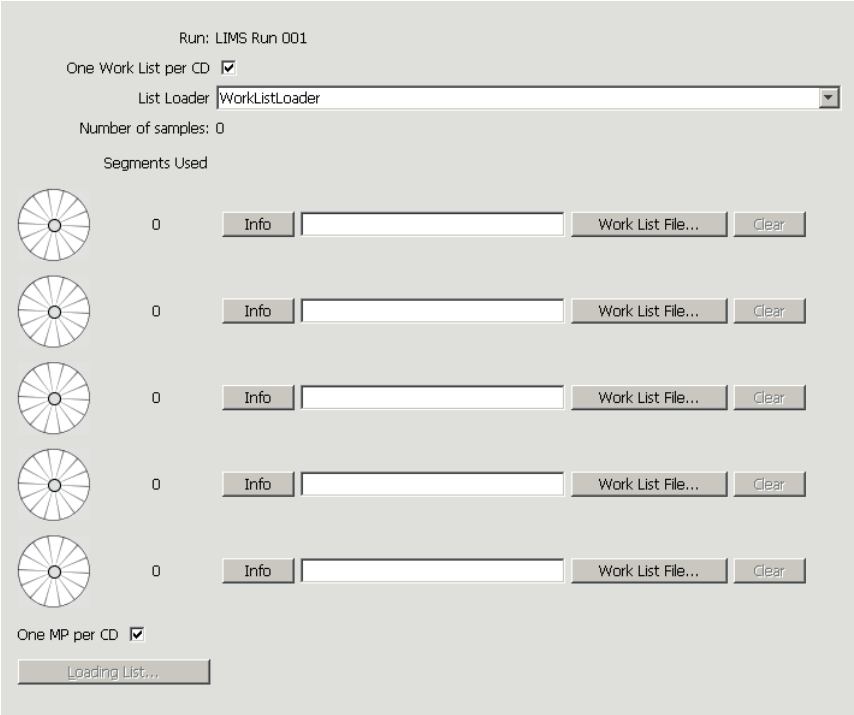
In your LIMS, generate one or more worklists to be processed in the LIMS Run. Standards, Quality Controls and Unknown samples and their replicates are defined in the worklists. Note that your LIMS must generate worklists in certain formats in order to be able to interact with Gyrolab Control software. Contact Gyros for more information.

It is possible to make one LIMS worklist per CD or one LIMS worklist for all CDs in a Run.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

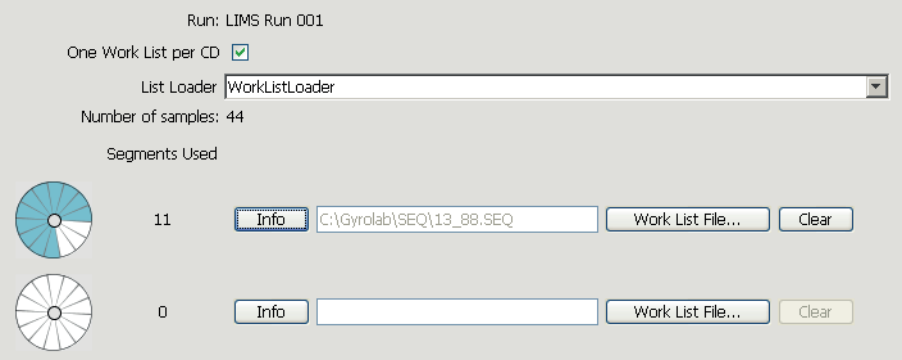
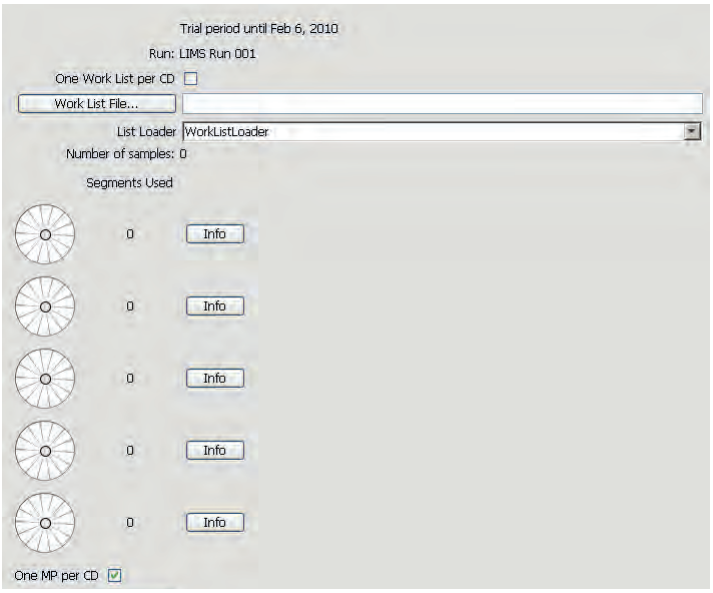
D3.4 Prepare LIMS Run

Step	Action
1.	Click **Execute Run** on the Main menu.
2.	Browse and select desired **Run** from the list and click **OK**. Runs that are not complete and thus not ready to execute, are marked with a zigzag line. More information is needed before the Run can be executed.
3.	A screen is opened. LIMS license and Run data is displayed.



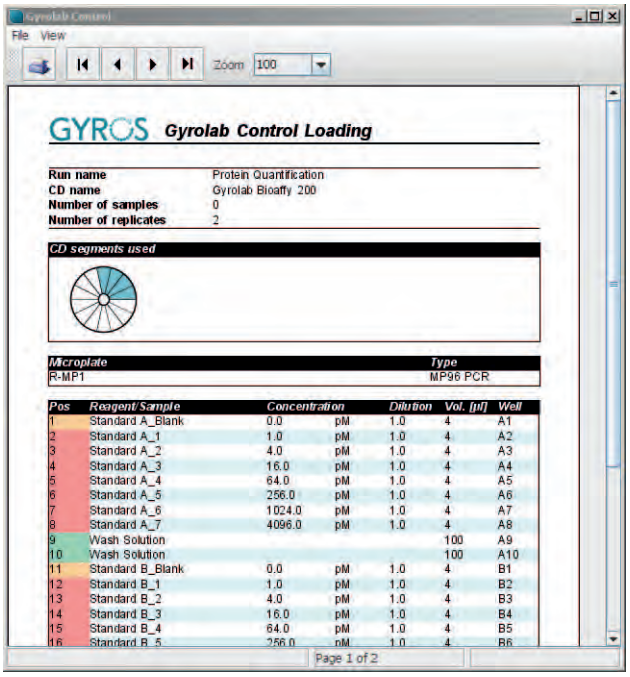
- **List Loader** file sets rules for how to import worklists. Choose the **WorkList-Loader** option in the drop down menu.
- Define number of work lists:
  - Check **One Work List per CD** box if multiple work lists (one per CD) has been defined in the LIMS. Go to step 4.
  - Un-check **One Work List per CD** box if one worklist is used for all CDs. Go to step 5.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
4.	Option "one Work List per CD": For each CD and worklist: • Click **Work List File**. In the **Select Work List File** window, browse and select Work List for current CD. • Required CD segments is shown in the CD symbol. • Click **Info** for CD of interest to view sample information. Check Show replicate ID:s box to show information about sample replicates. • Click **Clear** to remove a Work List. • Continue to step 6. 
5.	Option "one Work List for all CDs": • Click **Work List File**. In the **Select Work List File** window, browse and select Work List. • Required CD segments per CD are shown in the CD symbols. • Click **Info** for CD of interest to view sample information. Check Show replicate ID:s box to show information about sample replicates. • Continue to step 6. 

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
6.	• Check **One MP per CD** to place all samples for one CD on individual microplates. • Un-check **One MP per CD** to let the software distribute samples on microplates.
7.	Click **Loading List**. **Gyrolab Control Loading** screen is opened.


File View
Zoom 100
GYROS Gyrolab Control Loading
Run name Protein Quantification
CD name Gyrolab Bioaffy 200
Number of samples 0
Number of replicates 2
CD segments used
Microplate Type
R-MP1 MP96 PCR
Pos Reagent/Sample Concentration Dilution Vol. [µl] Well
1 Standard A_Blank 0.0 pM 1.0 4 A1
2 Standard A_1 1.0 pM 1.0 4 A2
3 Standard A_2 4.0 pM 1.0 4 A3
4 Standard A_3 16.0 pM 1.0 4 A4
5 Standard A_4 64.0 pM 1.0 4 A5
6 Standard A_5 256.0 pM 1.0 4 A6
7 Standard A_6 1024.0 pM 1.0 4 A7
8 Standard A_7 4096.0 pM 1.0 4 A8
9 Wash Solution 100 A9
10 Wash Solution 100 A10
11 Standard B_Blank 0.0 pM 1.0 4 B1
12 Standard B_1 1.0 pM 1.0 4 B2
13 Standard B_2 4.0 pM 1.0 4 B3
14 Standard B_3 16.0 pM 1.0 4 B4
15 Standard B_4 64.0 pM 1.0 4 B5
16 Standard B_5 256.0 pM 1.0 4 B6
Page 1 of 2

- **Gyrolab Control Loading** holds microplate loading information and is used when preparing microplates for a run. Name, concentration, volume, microplate and well position is included for all sample types. An overview of microplates with indication of used wells is also provided.
- Click **Printer** button to print the **Gyrolab Control Loading**.

TIP: ***Select* File: Export *to export the Loading list in PDF or text format. This is useful when printing from another computer is required.***

8. Close **Gyrolab Control Loading**.

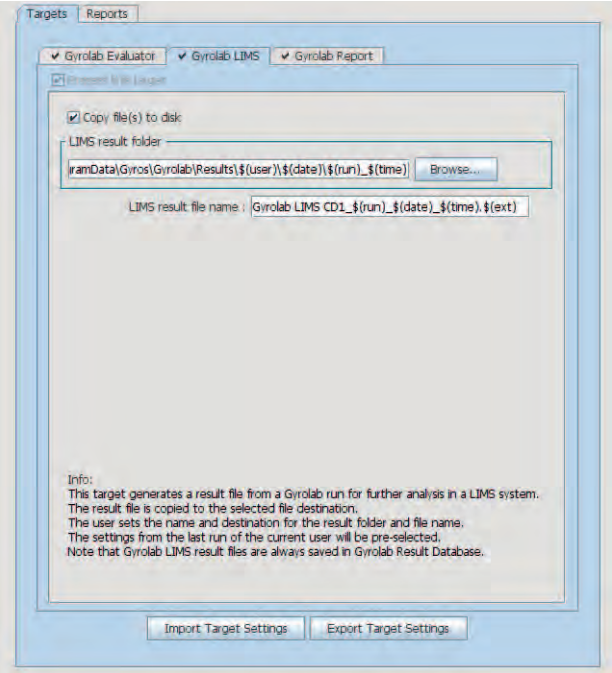
9. Click **OK**. A screen with two tabs, **Targets** and **Reports**, is opened.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

10. In the **Targets** tab, choose **Gyrolab LIMS**.

LIMS result files are always saved in Gyrolab Result Database. To create local copies of the LIMS result files (optional), mark the check box **Copy file(s) to disc.**


Targets
Reports
Gyrolab Evaluator
Gyrolab LIMS
Gyrolab Report
Copy file(s) to disk
LIMS result folder
ramData\Gyros\Gyrolab\Results\$(user)\$(date)\$(run)_$(time)
Browse...
LIMS result file name :
Gyrolab LIMS CD1_$(run)_$(date)_$(time).$(ext)
Info:
This target generates a result file from a Gyrolab run for further analysis in a LIMS system.
The result file is copied to the selected file destination.
The user sets the name and destination for the result folder and file name.
The settings from the last run of the current user will be pre-selected.
Note that Gyrolab LIMS result files are always saved in Gyrolab Result Database.
Import Target Settings
Export Target Settings

Files are saved to the location specified in **LIMS result folder** field and with the name specified in **LIMS result file name**. Settings are preserved from the user's last Run.

- To import default settings for **LIMS result folder** and **LIMS result file name**:
  - Click **Import Target Settings**.
  - In the **Import Settings** dialog, browse to `C:\ProgramData\Gyros\Gyrolab\Templates\Default Settings`, select **LIMSTargetSettings.xml** and click **Import**.
- To customize settings for **LIMS result folder** and **LIMS result file name**:
  - To edit **LIMS result folder**, click **Browse**. Browse and click **Select** to set new folder in the **Select folder** dialog.
  - To edit **LIMS result file name**, click in the field and edit.

TIP: ***Macros can be used to construct file names and locations, refer to Chapter B3.1.5 for a list of available macros.***

TIP: ***The settings in the Targets tab can be exported and imported, which enables settings to be shared between users, instruments and projects.***

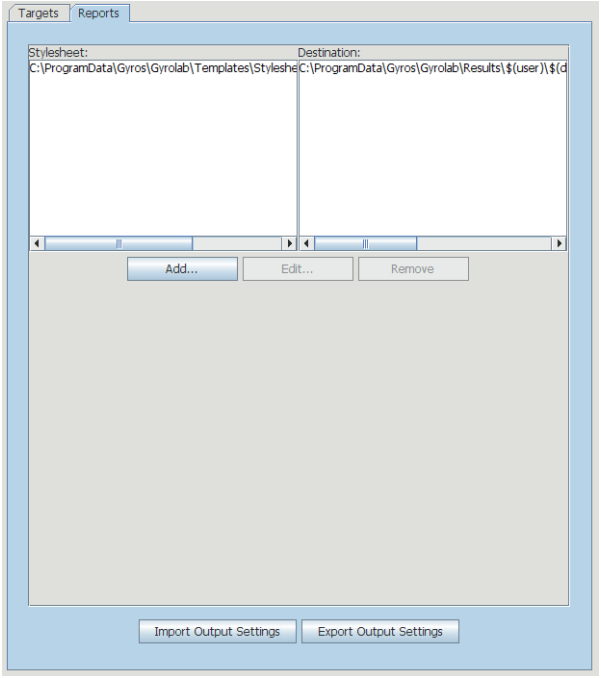
11. Other targets tabs may be available as well, for example Gyrolab Report.

The **Gyrolab Report** tab contains settings specific for the software module Gyrolab Control Report and is only available if a licence for Gyrolab Control Report has been acquired. Refer to Chapter D4.2 for more information.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

12. Open **Reports** tab.



A report file, with information on the Run, can be generated.

- To import default settings for report file **Stylesheet** and **Destination**:
  - Click **Import Output Settings**.
  - In the **Import Settings** dialog, browse to `C:\ProgramData\Gyros\Gyrolab\Templates\Stylesheets`, select **GyrolabStandardReport.xsl** and click **Import**.
- If no report file is wanted, select the file present in **Stylesheet** and click on **Remove** button.

TIP: ***Customized reports can be generated. Contact Gyros for information.***

13. Click **OK** and proceed to Chapter B4.1.1 (Gyrolab xP) or Chapter B4.2.1 (Gyrolab xPlore), sample and reagents preparations.

D3.5 Gyrolab LIMS Interface data output

One or more LIMS Run result files are generated in the format specified in Chapter D3.2 and to location specified in Chapter D3.4. The result files can be imported into a LIMS for analysis.

D3.6 Data evaluation

When using the LIMS workflow, all data analysis is performed using a LIMS system.

D3.7 Installation of Gyrolab LIMS Interface

The Gyrolab LIMS Interface software module is available for Gyrolab Control version 5.2 or higher and is activated by the user with a licence key. Licenses are instrument specific. Contact Gyros to purchase Gyrolab LIMS Interface and receive a license.

To register the license: Save the license file to the hard disk of the instrument computer at the destination: `C:\ProgramData\Gyros\Licenses`.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D4 Gyrolab Control Report

Visit www.gyros.com for the latest updates on available software modules.

D4.1 Introduction to Gyrolab Control Report

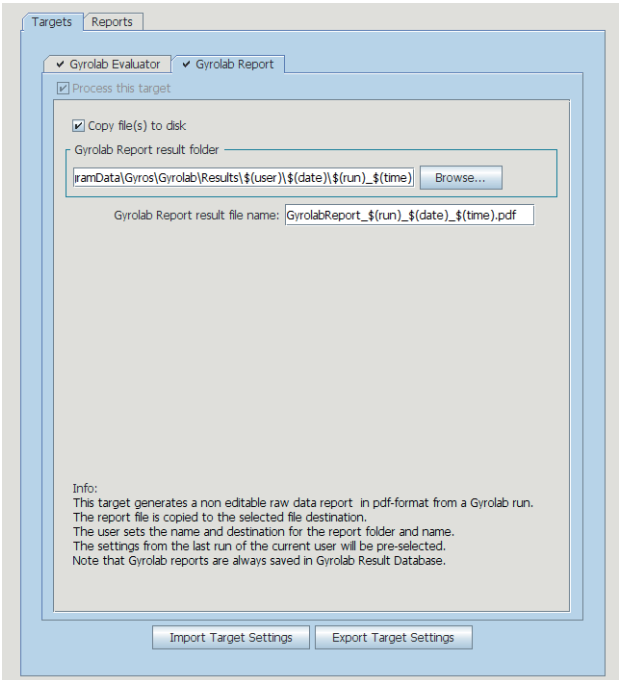
Gyrolab Control Report is a software add-on module for Gyrolab Control version 5.2 or higher that enables automatic generation of a condensed, printable, raw data report in pdf format after each run on the Gyrolab instrument. The generated report is compliant with 21 CFR Part 11 regulations and cannot be edited. The report includes raw data and general information about the run and experimental details.

The software was developed to support users whose workflows require non-editable and printable raw data reports.

D4.2 Perform run using Gyrolab Control Report

After installation of Gyrolab Control Report module, during preparation of the first Gyrolab run, it is necessary to import target settings for the Gyrolab Control Report module. Unless it is desired to change location for the Gyrolab Control Report file at a later time, these settings need only be performed once for each user.

Step	Action
1.	Prepare the run and edit settings for targets as described in Chapter B3.1.4 (Gyrolab xP) or Chapter B3.2.4 (Gyrolab xPlore). When the target screen is reached, go to target tab **Gyrolab Report**. Gyrolab Control Report result files from the run are always saved in Gyrolab Result Database. To create local copies of the result files (optional), mark the check box **Copy file(s) to disc.**


Targets
Reports
Gyrolab Evaluator
Gyrolab Report
Process this target
Copy file(s) to disk
Gyrolab Report result folder
ramData\Gyros\Gyrolab\Results\$(user)\$(date)\$(run)_$(time)
Browse...
Gyrolab Report result file name:
GyrolabReport_$(run)_$(date)_$(time).pdf
Info:
This target generates a non editable raw data report in pdf-format from a Gyrolab run.
The report file is copied to the selected file destination.
The user sets the name and destination for the report folder and name.
The settings from the last run of the current user will be pre-selected.
Note that Gyrolab reports are always saved in Gyrolab Result Database.
Import Target Settings
Export Target Settings

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
2.	Files are saved to the location specified in **Gyrolab Report result folder** field and with the name specified in **Gyrolab Report result file name**. Settings are preserved from the user's last Run.

- To import default settings for **Gyrolab Report result folder** and **Gyrolab Report result file name**:
  - Click **Import Target Settings**.
  - In the **Import Settings** dialog, browse to `C:\ProgramData\Gyros\Gyrolab\Templates\Default Settings`, select **GyrolabReportTargetSettings.xml** and click **Import**.
- To customize settings for **Gyrolab Report result folder** and **Gyrolab Report result file name**:
  - To edit **Gyrolab Report result folder**, click **Browse**. Browse and click **Select** to set new folder in the **Select folder** dialog.
  - To edit **Gyrolab Report result file name**, click in the field and edit.

NOTE: ***The maximum number of characters in folder name and file name is 30, including file extension. Do not begin the folder name and/or file name with a number.***

TIP: ***Macros can be used to construct file names and locations, refer to Chapter B3.1.5 (Gyrolab xP) or to Chapter B3.1.5 (Gyrolab xPlore) for a list of available macros.***

TIP: ***The settings in the Targets tab can be exported and imported, which enables settings to be shared between users, instruments and projects.***

3.	Continue with target settings for other modules as described in step 7 in Chapter B3.1.4. (Gyrolab xP) or to Chapter B3.2.4 (Gyrolab xPlore) and with run preparations, start and finish as described throughout Section B in Gyrolab User Guide. When the run has finished, Gyrolab Control will generate an output report file in pdf format including specific information about the run.

D4.3 Gyrolab Control Report output

The report file is automatically placed in the Gyrolab Result Database. A copy of the report is, if requested by the user, placed at the location specified by in the target setting, refer to Chapter D4.2.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

The following run, experiment and sample information is included:

Run information
Date and Time
Run by
Method
Design type
Experiments
Sample, reagent, transfer list (file name/s)
Detect operations
Instrument name
Database name
Gyrolab Control version

Experiment information
Sample identity
Replicate number
Sample type
MP id
MP well
CD id
CD structure
Gyrolab response

D4.4 Installation of Gyrolab Control Report

The Gyrolab Control Report software module is available for Gyrolab Control version 5.2 or higher and is activated by the user with a licence key. Licenses are instrument specific. Contact Gyros to purchase Gyrolab Control Report and receive a license.

To register the license: Save the license file to the hard disk of the instrument computer at the destination: `C:\ProgramData\Gyros\Licenses`.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D5 Gyrolab Serial Dilution Analysis

Visit www.gyros.com for the latest updates on available software modules.

D5.1 Introduction

Gyrolab Serial Dilution Analysis is a software add-on module for Gyrolab Evaluator version 3.2 or higher. The software is used for automatic evaluation of spike recovery to verify the sample analysis accuracy using dilution series of spiked and unspiked unknown samples.

Gyrolab Serial Dilution Analysis loads data from the quantification analysis using the information in the analysis settings fields **Spiked subgroup prefix**, **Unspiked subgroup prefix** and **Requested PMT name**, refer to Chapter D5.5.

Data results of unspiked and spiked aliquotes for different dilutions are paired. Only data from PMTs with names that match the requested PMT name will be included in the analysis.

D5.2 Create Run

Create the Run using the Wizard workflow (Chapter B3.1.2 (Gyrolab xP) or Chapter B3.2.2 (Gyrolab xPlore)) or the Custom workflow (Chapter H2). To enable analysis with Gyrolab Serial Dilution Analysis, certain conditions apply to the Sample List:

- **Sample Identity** must be the same for all dilutions of the same sample.
- **Sample Subgroup** is mandatory and used to pair spiked and unspiked samples of the same dilution factor. The Subgroup shall be set to Unspiked_1 and Spiked_1 for the first dilution pair within a sample, Unspiked_2 and Spiked_2 for the second dilution pair within the same sample and so on. An example is given in Figure 1.
- **Dilution factor** is mandatory to enable calculations.

For information on the other Sample List fields, refer to Chapter B3.1.3 (Gyrolab xP) or Chapter B3.2.3 (Gyrolab xPlore).

Template version:	Sample3.0		**Sample list info**				
M=Mandatory	**Sample MP Type (M)**	MP96 PCR					
O=Optional	**Result File Name (O)**						
N/A=Not Applicable	**Result File Path (O)**						
Index (M)/(N/A)	**Sample Type (M)**	**Sample Identity (M)**	**Sample Group (O)**	**Sample Subgroup (O)**	**Dilution Factor (O)**	**MP Identity (M)**	**Well (M)**
#1	UNK	X		Unspiked_1	2	MP1	A1
#2	UNK	X		Unspiked_2	4	MP1	A2
#3	UNK	X		Unspiked_3	8	MP1	A3
#4	UNK	X		Unspiked_4	16	MP1	A4
#5	UNK	X		Spiked_1	2	MP1	A5
#6	UNK	X		Spiked_2	4	MP1	A6
#7	UNK	X		Spiked_3	8	MP1	A7
#8	UNK	X		Spiked_4	16	MP1	A8
#9	UNK	Y		Unspiked_1	5	MP1	B1
#10	UNK	Y		Unspiked_2	10	MP1	B2
#11	UNK	Y		Spiked_1	5	MP1	B3
#12	UNK	Y		Spiked_2	10	MP1	B4

Figure 1: Example of a Sample List for a Run analyzed with Gyrolab Serial Dilution Analysis.

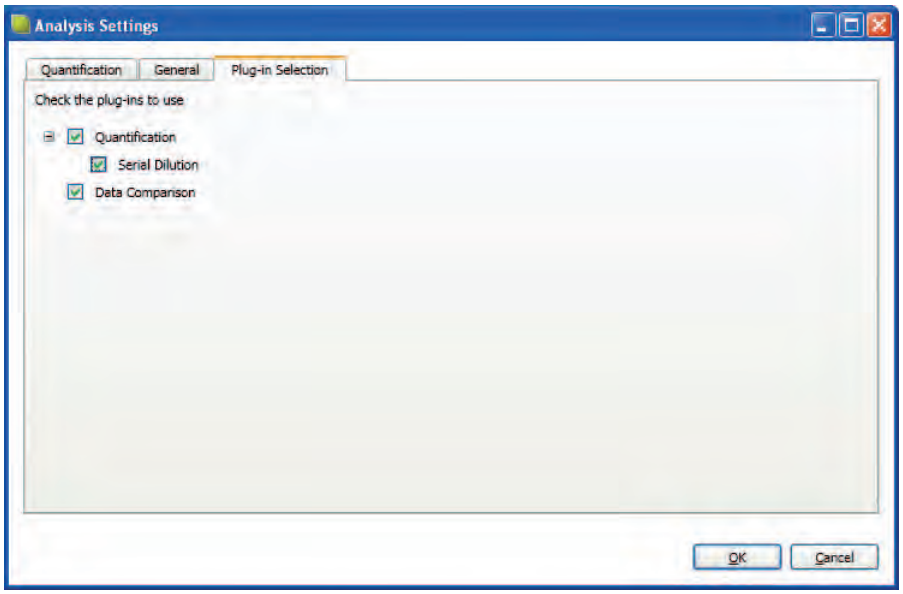
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D5.3 Perform serial dilution analysis

To set default analysis parameters and/or to lock the settings for a Project, refer to Chapter C3.8.

Step	Action

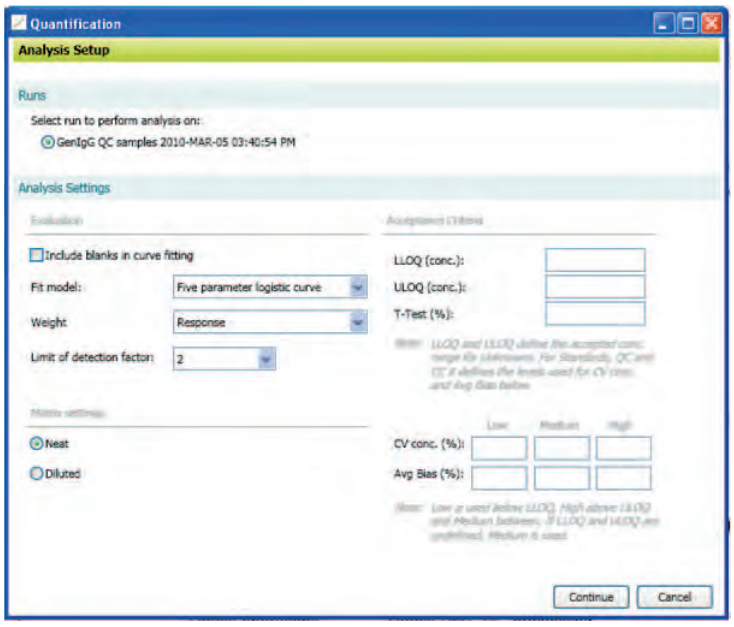
1. To activate Gyrolab Serial Dilution Analysis, go to **View:Analysis settings** and select the tab **Plug-in Selection** and mark the check box **Serial Dilution**.



Close the Analysis settings window.

2. In the Project view (Chapter C3.1), click the **Quantification** button.

3. The **Analysis Settings** window opens. The basic analysis settings are described in Chapter C4.4. Edit settings as desired. Click **OK**.



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

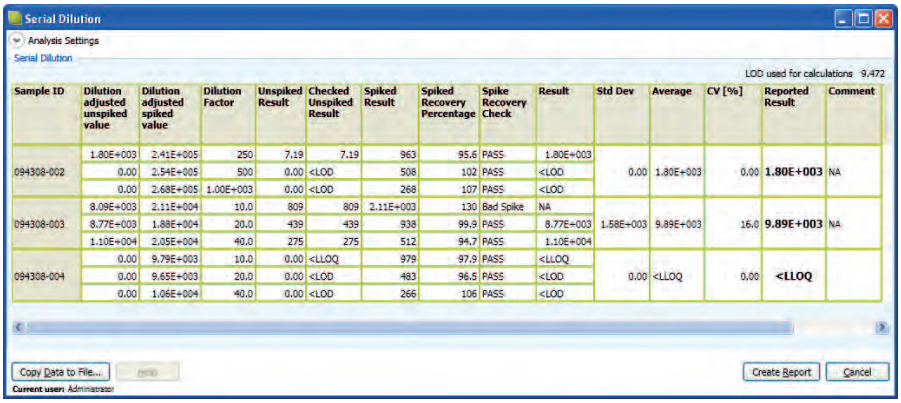
4. The **Quantification** window opens.

This window holds all the same functionality as the Quantification module. Left panel shows available experiments and right panel holds analysis settings, data tables and a chart. It is possible to add notes and to copy data to file.

Quantification module and available settings and tools are described in more detail in Chapter C4.1.

5. Click **Next**.

6. The **Serial Dilution** window opens. This window holds the analysis results that are specific to Gyrolab Serial Dilution Analysis.



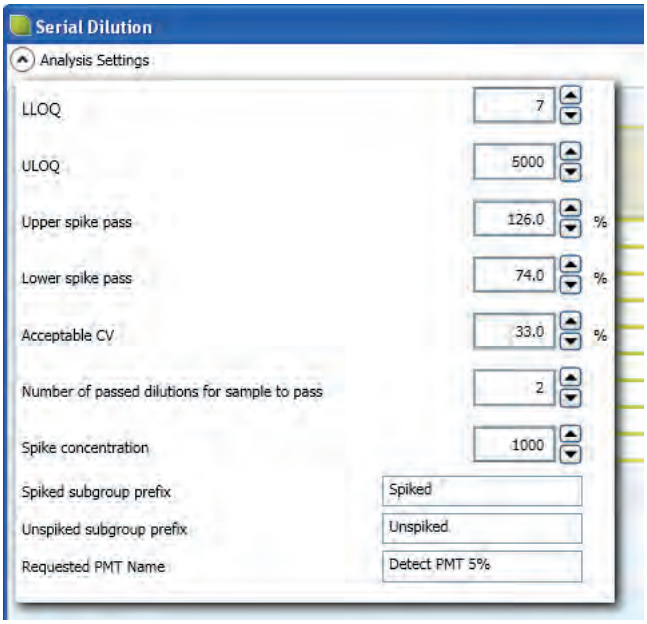
Sample ID	Dilution adjusted unspiked value	Dilution adjusted spiked value	Dilution Factor	Unspiked Result	Checked Unspiked Result	Spiked Result	Spiked Recovery Percentage	Spike Recovery Check	Result	Std Dev	Average	CV [%]	Reported Result	Comment
	1.80E+003	2.41E+005	250	7.19	7.19	963	95.6	PASS	1.80E+003					
094308-002	0.00	2.54E+005	500	0.00	<LOD	508	102	PASS	<LOD	0.00	1.80E+003	0.00	**1.80E+003**	NA
	0.00	2.68E+005	1.00E+003	0.00	<LOD	268	107	PASS	<LOD					
	8.09E+003	2.11E+004	10.0	809	809	2.11E+003	130	Bad Spike	NA					
094308-003	8.77E+003	1.88E+004	20.0	439	439	938	99.9	PASS	8.77E+003	1.58E+003	9.89E+003	16.0	**9.89E+003**	NA
	1.10E+004	2.05E+004	40.0	275	275	512	94.7	PASS	1.10E+004					
	0.00	9.79E+003	10.0	0.00	<LLOQ	979	97.9	PASS	<LLOQ					
094308-004	0.00	9.65E+003	20.0	0.00	<LOD	483	96.5	PASS	<LOD	0.00	<LLOQ	0.00	**<LLOQ**	
	0.00	1.06E+004	40.0	0.00	<LOD	266	106	PASS	<LOD					

- In the **Serial Dilution** list, Unknown samples and analysis result are listed. Values that fall outside of acceptance criteria set in step 3 are indicated by red cell background color.
- For data columns definitions, refer to Chapter D5.4.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

7. Click **Settings** to view and/or edit settings for Gyrolab Serial Dilution Analysis. Refer to Chapter D5.5 for information on the different parameters.



- By changing parameters settings the approved/unapproved status for the Unknown samples listed in the **Serial Dilution** list may change.
- Click **Settings** again to close the **Settings** view.

8. Optional: To copy data from Gyrolab Serial Dilution Analysis in text format (.txt), click **Copy Data To File** button and browse for desired location and click **Save**.

9. Click **Create Report**.

10. Set **Analysis Name** and click **OK**.

11. The analysis is now saved under **Analyses:Quantification** in Gyrolab Evaluator Project view. Expand the structure under the Quantification Report to access the **Serial Dilution Report**. The functionality for exporting analysis reports in .xps format is not available for the Serial Dilution Report.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D5.4 Gyrolab Serial Dilution Analysis data table description

Description of result data displayed by Gyrolab Serial Dilution Analysis is available in the table below. Number of columns displayed may differ depending on available sample results and type of sample.

Column heading	Description
Sample ID	The sample ID, common for a number of sample dilutions.
CD ID	Identity of Gyrolab CD microlaboratory used to process the samples.
Dilution adjusted unspiked value	Average concentration of unspiked (spiked) replicates multiplied by the dilution factor.
Dilution adjusted spiked value	The average concentration of the spiked sample. The concentration used is multiplied with the Dilution Factor.
Dilution Factor	Dilution Factor is multiplied with calculated concentration. Dilution Factor is defined in sample list. If no Dilution Factor has been given the value will automatically be 1.
Unspiked Results	The average concentration of analyte in unspiked sample replicates without multiplying by the dilution factor.
Checked Unspiked Results	The concentration from the **Unspiked Result** column checked against LOD value, the Lower Limit of Quantitation and the Upper Limit of Quantitation. The reported value will be <LOD, <LLOQ or >ULOQ if the value falls outside of the acceptance criteria.
Spiked Results	The average concentration of analyte in spiked sample replicates without multiplying by the dilution factor
Spiked Recovery Percentage	The **Spiked Result** divided by the Spike analyte concentration multiplied by 100.
Spike Recovery Check	The Spike recovery percentage checked against the values for lowest and highest acceptable spike recovery. Value is either "Bad Spike" or "Pass".
Result	Either the calculated mean analyte concentration among replicates or the disposition of the sample based on user input sample analysis parameters i.e. NA (for Bad Spike), <LLOQ, <LOD or >ULOQ
Std Dev	The standard deviation of **Dilution adjusted unspiked value** between the serial dilutions. Values are only used if they fall between the LLOQ and ULOQ and have passing spike recoveries
Average	The average of **Dilution adjusted unspiked value** between the serial dilutions. Values are only used if they fall between the LLOQ and ULOQ and have passing spike recoveries
CV (%)	The coefficient of variation of **Dilution adjusted unspiked value** between the serial dilutions. Values are only used if they fall between the LLOQ and ULOQ and have passing spike recoveries

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Column heading	Description
Reported Results	The main result column. The average analyte concentration over all passing dilutions of a sample. Results are only reported if they meet CV requirements and if the number of passing dilutions exceeds the user input number. If no reportable numerical results exist, the value will be either <LLOQ, <LOD, >ULOQ or Retest i
Comment	Space to input any necessary comments about samples

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D5.5 Analysis settings for Gyrolab Serial Dilution Analysis

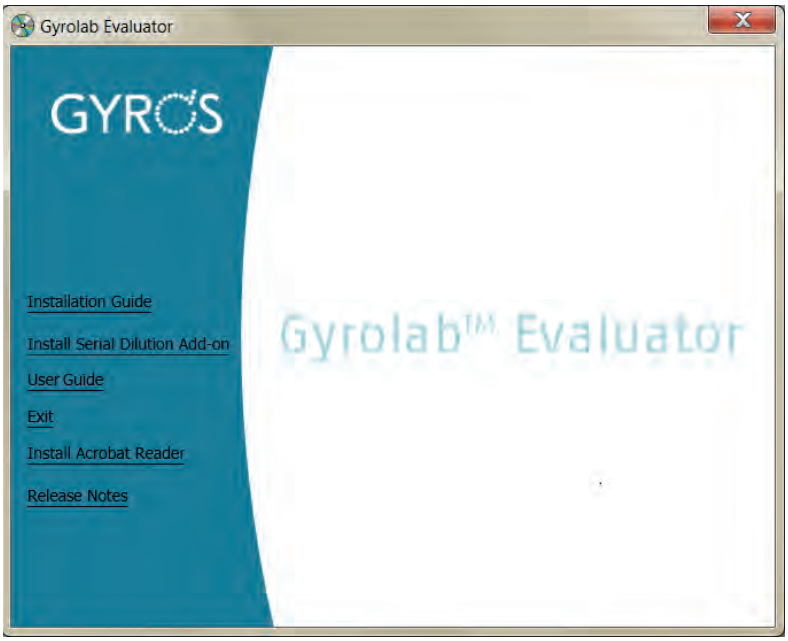
The table below describes available analysis settings for Projects and analyses when analyzing with Gyrolab Serial Dilution Analysis.

Parameter	Comment
LLOQ	The lower limit for the assay, that is the LLOQ value. The value is the concentration value after dilution. Applied to the **Unspiked Results** column and reflected in the **Checked Unspiked Result** column.
ULOQ	The upper limit for the assay. The value is the concentration value after dilution. Applied to the **Unspiked Results** column and reflected in the **Checked Unspiked Result** column.
Upper spike pass	Highest acceptable value for the spiked recovery percentage.
Lower spike pass	Lowest acceptable value for the spiked recovery percentage.
Acceptable CV	The maximal acceptable CV.
Spike concentration	The concentration in the spike that was added to the sample (1000 ng/mL in the example below). Example: The initial spiked sample dilution is prepared by adding 50 µL of sample + 50 µL of 2000 ng/mL protein X (for a final concentration of spike = 1000 ng/mL). The unspiked sample is prepared by adding 50 µL of sample + 50 µL of sample diluent. The initial dilution is then serially diluted 2-fold twice. The spiked concentration in the second dilution should be 500 ng/mL and 250 ng/mL in the third.
Spike subgroup prefix	The prefix used to identify spiked samples. Specified in the Subgroup column in the Sample list used when executing the Run.
Unspiked subgroup prefix	The prefix used to identify unspiked samples. Specified in the Subgroup column in the Sample list used when executing the Run.
Requested PMT Name	The PMT-setting that the analysis will be performed on.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

D5.6 Installation of Gyrolab Serial Dilution Analysis

The Gyrolab Serial Dilution Analyis software module is compatible with Gyrolab Evaluator version 3.2 or higher and is installed by the Gyrolab user. Contact Gyros to purchase Gyrolab Serial Dilution Analysis and receive an installation CD.

Step	Action
1.	Insert Gyrolab Serial Dilution Analysis installation CD in the CD drive. ***NOTE: Gyrolab Evaluator must be installed on the computer prior to installation of Gyrolab Serial Dilution Analysis.***
2.	**Gyrolab Serial Dilution Analysis** installation screen opens.  If the installation start screen does not appear automatically, browse for the CD folder in Windows Explorer and double-click on the file **\splash\autorun.exe**.
3.	• Select **Installation Guide** to view installation instructions. • Select **User Manual** to access Gyrolab User Guide. • Select **Exit** to exit installation procedures. • Select **Install Acrobat Reader** and follow the instructions to install Acrobat Reader. This is needed only if your system does not have a pdf reader already. • Select **Release Notes** to view information on this software release.
4.	Select **Install Serial Dilution Add-on** to start installation. Follow the instructions in the installation wizard.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

GYROLAB USER GUIDE

E Recipes

Contents

E1 Recipes E-3

E1.1 Stock solutions E-3

E1.2 Working solutions E-5

E1.2.1 Bioaffy Pump Liquid E-5

E1.2.2 Bioaffy Wash Station Solution 1 . . . . . E-5

E1.2.3 Bioaffy Wash Station Solution 2 . . . . . E-5

E1.2.4 Standby Solution E-7

E1.2.5 Needle Sanitize Solution E-7

E1.2.6 Wash Station Sanitize Solution E-7

E1.2.7 Needle Desorb Solution E-8

E1.2.8 General buffers E-9

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

E1 Recipes

In this chapter recipes for Gyrolab Runs, maintenance and sanitization procedures are provided.

E1.1 Stock solutions

10% Tween 20

To prepare 100 ml	Dissolve 10 g Tween 20 in 90 g deionized/distilled water.
Storage	Store at room temperature up to six months and keep protected from light.

20% sodium azide (NaN_3)

WARNING: Sodium azide (NaN_3) is very toxic. Handle with care.

To prepare 100 ml	• Add 20 g NaN_3 to 100 g Milli-Q water. • Stir for 20 hours.
Storage	Store in a hood at room temperature for up to 1 year.

10x PBS with sodium azide

WARNING: Sodium azide (NaN_3) is very toxic. Handle with care.

Composition	150 mM phosphate buffer, 1.5 M NaCl, 0.2% NaN_3, (150 mM PBS).:
Chemicals required (1000 ml)	• 3.4 g NaH_2PO_4 (Mw 120 g/mol) • 17.3 g Na_2HPO_4 (Mw 142 g/mol) • 87.6 g NaCl (Mw 58.44 g/mol)
To prepare 1000 ml	• Dissolve all chemicals in 1000 ml deionized/distilled water. • Add 10 ml 20% NaN_3.
pH	1x PBS should have pH 7.4.
Storage	Store at room temperature.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

10x PBS	
Composition	150 mM phosphate buffer, 1.5 M NaCl, (150 mM PBS).:
Chemicals required (1000 ml)	• 3.4 g NaH_2PO_4 (Mw 120 g/mol) • 17.3 g Na_2HPO_4 (Mw 142 g/mol) • 87.6 g NaCl (Mw 58.44 g/mol)
To prepare 1000 ml	• Dissolve all chemicals in 1000 ml deionized/distilled water. • Filter buffer through 0.22 µm filter and store at room temperature.
pH	1x PBS should have pH 7.4.
Storage	Store at room temperature.

Use of pre-made PBS (1x or 10x)

Pre-made PBS can be used in the Gyrolab instrument provided that the buffer composition is according to our recommendations stated above.

Additional important aspects regarding pre-made PBS buffer:

- It should be free of Ca^{2+} and Mg^{2+}.
- Add Sodium azide prior to connecting the PBS buffer to the Gyrolab instrument.

NOTE: ***For PBS buffers, ensure they are filtered through 0.22 µm filter prior to connection to the Gyrolab instrument. Store at room temperature.***

1 M Sodium bicarbonate buffer stock	
Composition	1 M $NaHCO_3$
To prepare 1 ml	Add 1 ml deionized water to 85 mg of $NaHCO_3$.
Storage	Store at +4 °C for maximum two weeks.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

E1.2 Working solutions

E1.2.1 Bioaffy Pump Liquid

1 × PBS, 0.02% NaN3, 0.01% Tween 20	
Purpose	Used for the five Syringe Pumps.
Composition	15 mM phosphate buffer, 150 mM NaCl, 0.02% NaN_3, 0.01% Tween 20
To prepare 250 ml	• Mix 25 ml 10x PBS with 0.2% NaN_3 with 225 ml deionized/distilled water. • Add 250 µl 10% Tween 20.
Required volume	250 ml is needed for 1–5 CDs.

E1.2.2 Bioaffy Wash Station Solution 1

1 × PBS, 0.02% NaN3, 0.01% Tween 20	
Purpose	Used for the Wash Station
Composition	15 mM phosphate buffer, 150 mM NaCl, 0.02% NaN_3, 0.01% Tween 20
To prepare 1000 ml	• Mix 100 ml 10x PBS with 0.2% NaN_3 with 900 ml deionized/distilled water. • Add 1 ml 10% Tween 20.
Required volume	• 1000 ml for 1 CD • 2000 ml for 2–5 CDs

E1.2.3 Bioaffy Wash Station Solution 2

Select option depending on application.

Gyrolab Wash Buffer pH 11	
Purpose	Used for the Wash Station 2
Composition	Gyrolab Wash Buffer pH 11
To prepare 1000 ml	• Dissolve one pack (10 g) of Gyrolab Wash buffer pH 11 powder in 1000 ml deionized/destilled water. • Filter 0.22 µm
Required volume	• 1000 ml for 1 CD • 2000 ml for 2–5 CDs

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

50 mM Glycin pH 9.5 with 0.5% Dodecylsulfate sodium salt (SDS	
Purpose	Used for the Wash Station 2
Composition	50 mM Glycin pH 9.5 with 0.5% Dodecylsulfate sodium salt (SDS)
To prepare 1000 ml	• Dissolve 3.75 g Glycin in approximate 800 ml deionized/distilled water. • Adjust to pH 9.5 using sodium hydroxide. • Filter 0.22 µm • Dissolve 5 g Dodecylsulfate sodium salt (SDS, Mw 288,38 g/mol) and adjust the volume to 1000 ml.
Required volume	• 1000 ml for 1 CD • 2000 ml for 2–5 CDs

1.5 M NaCl, 20% ethanol	
Purpose	Used for the Wash Station 2
Composition	1.5 M NaCl in 20% ethanol
To prepare 1000 ml	• Mix 200 ml 95% ethanol with 800 ml deionized/distilled water. • Dissolve 87.66 g NaCl (Mw 58.44 g/mol) • Filter 0.22 µm
Required volume	• 1000 ml for 1 CD • 2000 ml for 2–5 CDs

0.5% Dodecylsulfate sodium salt (SDS), 20% ethanol	
Purpose	Used for the Wash Station 2
Composition	0.5% SDS in 20% ethanol
To prepare 1000 ml	• Mix 200 ml 95% ethanol with 800 ml deionized/distilled water. • Dissolve 5 g SDS (Mw 288.38 g/mol) • Filter 0.22 µm
Required volume	• 1000 ml for 1 CD • 2000 ml for 2–5 CDs

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

E1.2.4 Standby Solution

20% ethanol	
Purpose	To be used in Syringe Pumps
Composition	20% ethanol
To prepare 250 ml	Prepare 20% solution
Required volume	250 ml is needed to process 1–5 CDs.

E1.2.5 Needle Sanitize Solution

3% sodium hypochlorite	
Purpose	To be used for sanitizing needles.
Composition	3% sodium hypochlorite
To prepare 10 ml	Mix sodium hypochlorite with deionized/distilled water. The amount depends upon the concentration of the stock solution.

E1.2.6 Wash Station Sanitize Solution

3% sodium hypochlorite	
Purpose	To be used for sanitizing Wash Station 1 and 2.
Composition	3% sodium hypochlorite
To prepare 600 ml	Mix sodium hypochlorite with deionized/distilled water. The amount depends upon the concentration of the stock solution.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

E1.2.7 Needle Desorb Solution

	Gyrolab Wash Buffer pH 11
Purpose	To be used for Needle desorb
Composition	Gyrolab Wash Buffer pH 11
To prepare 1000 ml	Dissolve one pack (10 g) of Gyrolab Wash buffer pH 11 powder in 1000 ml deionized/destilled water. Filter through a 0.22 µm filter.

0.5% Dodecylsulfate sodium salt (SDS)	
Purpose	To be used for Needle desorb
Composition	0.5% SDS
To prepare 100 ml	Dissolve 0.5 g SDS in 99.5 g deionized/distilled water.

50 mM glycine, pH 9.5	
Purpose	To be used for Needle desorb
Composition	50 mM glycine, pH 9.5
To prepare 100 ml	Dissolve 375 mg glycine (Mw 75.07 g/mol) in 100 ml deionized/distilled water. Adjust to pH 9.5 with sodium hydroxide.

1.5 M NaCl in 20% ethanol	
Purpose	To be used for Needle desorb
Composition	1.5 M NaCl in 20% ethanol
To prepare 100 ml	Dissolve 8.77 g NaCl (Mw 58.44 g/mol) in 100 ml 20% EtOH. Filter through a 0.22 µm filter.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

E1.2.8 General buffers

PBS-T	
Purpose	PBS-T is a buffer for dilution of capture antibody and column wash in CDs.
Composition	15 mM phosphate buffer, 150 mM NaCl, 0.02% NaN_3, 0.01% Tween 20
To prepare 20 ml	• Mix 2 ml 10x PBS with 0.2% NaN_3, 20 µl 10% Tween 20 and 18 ml with deionized water. • Filter buffer through a 0.22 mm filter.
Storage	Store at +4 °C.

PBS-0.2% BSA	
Purpose	Storage buffer: Dilute Detecting reagent to 1000 nM after labeling
Composition	15 mM phosphate buffer, 150 mM NaCl, 0.02% NaN_3, 0.01% Tween 20
To prepare 20 ml	• Mix 2 ml 10x PBS with 0.2% NaN_3, 400 µl 10% BSA with 18 ml with deionized water. • Filter buffer through a 0.22 mm filter.
Storage	Store at +4 °C.

1 × PBS	
Purpose	During labelling of fluorophore and biotinylation.
Composition	15 mM phosphate buffer, 150 mM NaCl, 0.01% Tween 20
To prepare 20 ml	Mix 2 ml 10x PBS, 20 µl 10%.Tween 20 and 18 ml deionized water.
Storage	Store at +4 °C.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

GYROLAB USER GUIDE

F System administration and configuration

Contents

F1 Gyrolab Control. F-5

F1.1 Instructions for Gyrolab xP F-5

F1.1.1 Start Gyrolab Control..... F-5

F1.1.2 Gyrolab Control main menu..... F-6

F1.1.3 Main menu functions..... F-6

F1.2 Instructions for Gyrolab xPlore F-18

F1.2.1 Start Gyrolab Control..... F-18

F1.2.2 Gyrolab Control main menu..... F-19

F1.2.3 Main menu functions..... F-19

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2 Gyrolab Administration Tool F-29

F2.1 Login procedure F-29
F2.2 Gyrolab Administration Tool main menu F-30
F2.2.1 Design types F-31
F2.2.2 Folders F-33
F2.2.3 Runs F-35
F2.2.4 Methods F-37
F2.2.5 Maintenance F-39
F2.2.6 Users F-42
F2.2.7 CDs F-47
F2.2.8 Microplates F-49
F2.2.9 Liquids F-51
F2.2.10 Targets F-53
F2.2.11 List Loaders F-54
F2.2.12 About function F-56
F2.2.13 Logout F-56
F2.2.14 Help F-56

F3 Gyrolab Result Database Explorer F-57

F3.1 Introduction F-57
F3.2 View database files F-57
F3.3 Customize database view F-59
F3.4 Generate Result Reports F-61
F3.5 Generate Gyrolab Control Audit Trail report F-63
F3.5.1 Compressed Audit Trail report – Status Report F-63
F3.5.2 Readable Audit Trail Report – System Log Report F-64

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F4 Gyrolab Database Backup Manager F-65

F4.1 Perform Gyrolab database back up F-65

F4.2 Schedule Gyrolab data base backup F-66

F5 Gyrolab Set System Time F-67

F5.1 Gyrolab Set System Time introduction F-67

F5.2 Perform logged system time change F-67

F5.3 Non-logged system time changes F-68

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F1 Gyrolab Control

NOTE: ***There are two separate instructions, one for Gyrolab xP and one for Gyrolab xPlore.***

F1.1 Instructions for Gyrolab xP

F1.1.1 Start Gyrolab Control

The control software consists of the server and the client. The server must be running before starting the client.

Step	Action
1.	Start Gyrolab Server: • Click **Start:All Programs:Gyros:Server**. • **Gyrolab Instrument Log** is displayed and Gyrolab server icon appears on the task bar.
2.	Start Gyrolab Control software: • Select **Start:All Programs:Gyros:Client**.
3.	The **Login** dialog box is displayed. Enter user name and password in the **Login** dialog box. ***NOTE:*** ***User name and password are case sensitive.*** ***NOTE:*** ***The software will request the user to log in anew when the system has been inactive for 31 minutes.***
4.	Password must be changed when requested by Gyrolab Control. Password may also be changed when desired by a user: he **Change Password** window opens: • Enter present **Password**. • Enter **New Password**. • **Confirm Password**. • Click **OK**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
5.	Click **OK** to log in or **Exit** to close the dialog box without logging in. Once logged in, the main menu will appear.

F1.1.2 Gyrolab Control main menu

F1.1.2.1 Main menu overview

The start screen in Gyrolab Control holds the main menu from which all actions are initiated. The main menu also displays instrument access status (refer to Chapter F1.1.3), instrument mode (refer to Chapter F1.1.3.14) and functionality for alarm handling.

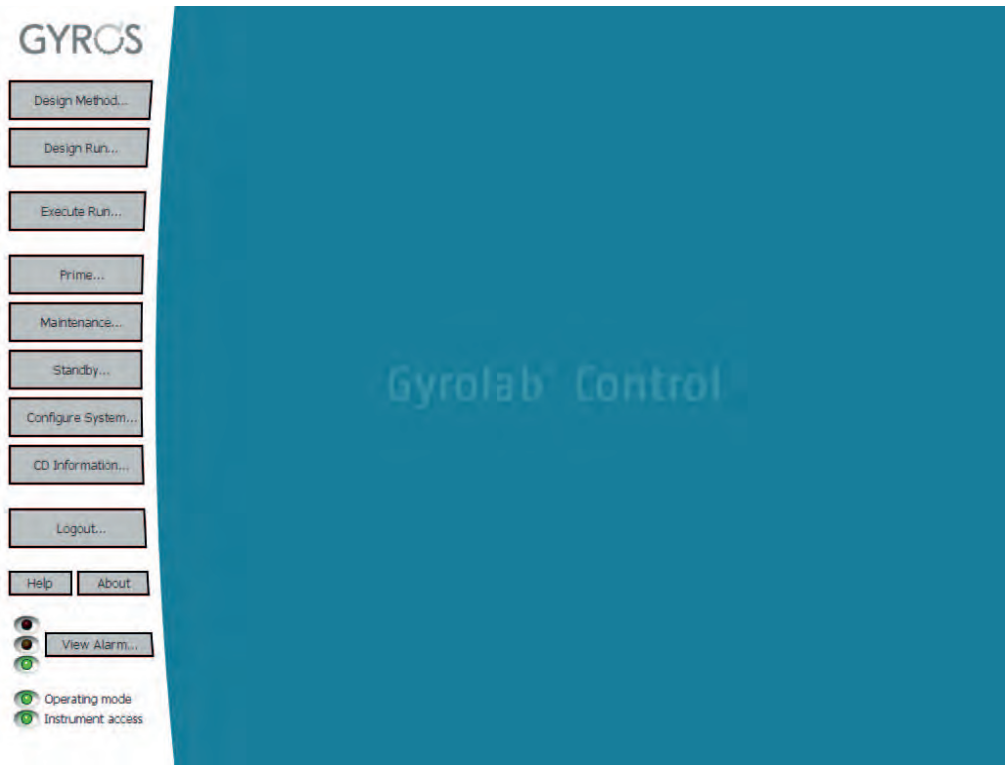


Figure 1: Main menu

The main functions of Gyrolab Control are represented by buttons on the main menu. Only one function at a time can be activated. Select a function by clicking on the function button and the panel for the selected function is displayed on the screen.

Buttons may be accessible (in the example above: **Initialize System**), inaccessible (in the example above: **Prime** button) or hidden (in the example above: **Execute Run** button).

F1.1.3 Main menu functions

Button/LED	Function
Design Method	Launches the **Design Method** screen to create new methods/edit method, refer to Chapter F1.1.3.1.
Design Run	Launches the **Design Run** screen to create new/edit/delete Runs, refer to Chapter F1.1.3.2

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Button/LED	Function
Execute Run	Launches the **Execute Run** screen to prepare and start a Run, Chapter F1.1.3.3
Prime	Launches the **Prime** screen to set priming parameters perform instrument priming, refer to Chapter F1.1.3.4
Maintenance	Launches the **Maintenance** screen to perform instrument priming and/or a cleaning method, refer to Chapter F1.1.3.5
Initialize System	Starts system initialization, refer to Chapter F1.1.3.6
Configure System	Launches the **Configure System** screen to change the system configuration, refer to Chapter F1.1.3.7
CD Information	Launches functionality to read information from a CD tag.
Logout	**Logout** from Gyrolab Control.
Help	Launches the help system, refer to Chapter F1.1.3.10
About	Displays information on software versions and licences, refer to Chapter F1.1.3.11
View Alarm	Displays information about alarms, refer to Chapter F1.1.3.12
Instrument access LED	Indicates instrument access status, refer to Chapter F1.1.3.13
Instrument mode LED	Indicates instrument mode, refer to Chapter F1.1.3.14

F1.1.3.1 Design Method

Design Method function is used for setting up new or edit existing Methods to be used in Runs. Methods can be customized by Gyros to suit specific needs. Contact Gyros for more information.

F1.1.3.2 Design Run

The information required to perform an immunoassay on the Gyrolab instrument is collected in a **Run**. The function **Design Run** is used to create, edit, and delete Runs. Input data for a Run differs depending on which design type (which type of Run) is used.

- For a detailed description of how to create or edit Wizard Runs, refer to Chapter B3.1.2 (Gyrolab xP) or Chapter B3.2.2. (Gyrolab xPlore).
- For a detailed description of how to create or edit LIMS Runs, refer to Chapter B3.1.5 (Gyrolab xP) or Chapter B3.2.5 (Gyrolab xPlore).

F1.1.3.3 Execute Run

Runs are prepared, loaded, executed, unloaded and finished in the **Execute Run** function. The run design is completed with sample information (Sample List) and settings for result and report files. Input data and settings differs depending on which design type (which type of Run) is used.

- For a detailed description of how to prepare and execute Wizard Runs, refer to Chapter B3.1.4 (Gyrolab xP) or Chapter B3.2.4 (Gyrolab xPlore).
- For a detailed description of how to prepare and execute LIMS Runs, refer to Chapter D3.
- For a detailed description of how to prepare and execute Custom Runs, refer to Chapter B3.1.4 (Gyrolab xP) or Chapter B3.2.4 (Gyrolab xPlore).

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F1.1.3.4 Prime

Instrument priming is performed through this function. Refer to Gyrolab Instrument Guide.

F1.1.3.5 Maintenance

Maintenance function is used for system maintenance. Refer to Gyrolab Instrument Guide for information about specific methods and procedures.

F1.1.3.6 Initialize System

Hardware tests of the components are performed during initialization, for example robot arm movements, carousel rotation and vacuum of the CD stations.

Step	Action
1.	Close the Gyrolab instrument hatch if open. Click **Initialize System** on the Main menu. The **Initializing System** dialog box is displayed as initialization proceeds.

Details of the initialization can be viewed by clicking on the **Details** button.

NOTE: ***To re-initialize the system, click on Logout in the Main menu. Choose Restart from the drop down menu in the Shut Down dialog, then click OK.***

2.	Click **Finish** when initialization is complete.

F1.1.3.7 Configure System

The Gyrolab instrument is delivered with a pre-programmed configuration set-up and system priming protocol. This section explains how to configure the system and alter these settings.

CAUTION: Contact Gyros before changing any configuration default settings.

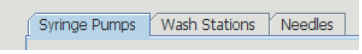
NOTE: ***Only user with user levels Method Developer or System Administrator can configure the system, refer to Chapter F2.2.6.***

Access the Configure System screen

Step	Action
1.	If the instrument is not initialized, click **Initialize** on the main menu. ***NOTE:*** ***The system must be initialized in order to access the Configure System screen.***
2.	Click the **Configure System** button on the main menu.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
3.	Select desired tab, refer to chapters "Configure Syringe Pumps" on page 9 to "Configure CD stations" on page 13 for further instructions.



Configure Syringe Pumps

The system is equipped with five Syringe Pumps that control two needles each. Pump number 1 controls needles 1 and 2, pump number 2 controls needles 3 and 4 and so on. This set-up is displayed on the **Syringe Pumps** tab in the **Configure System** screen.

NOTE: Different Syringe Pumps can handle different liquids.

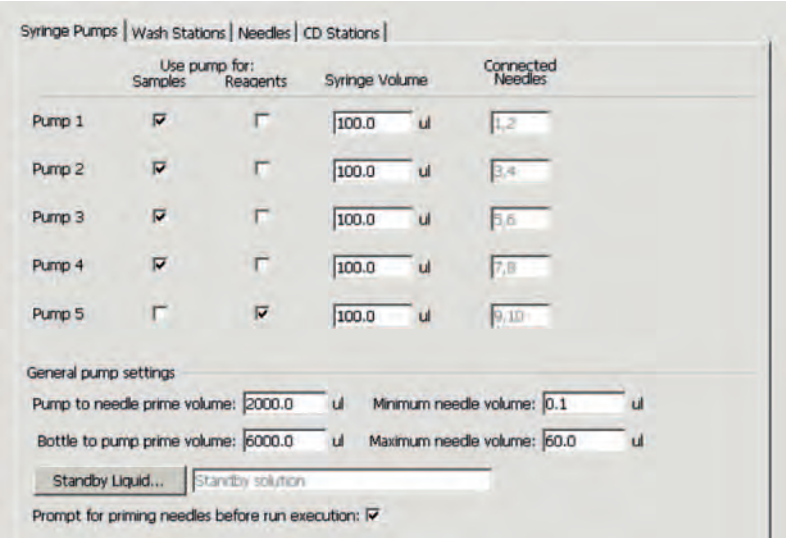
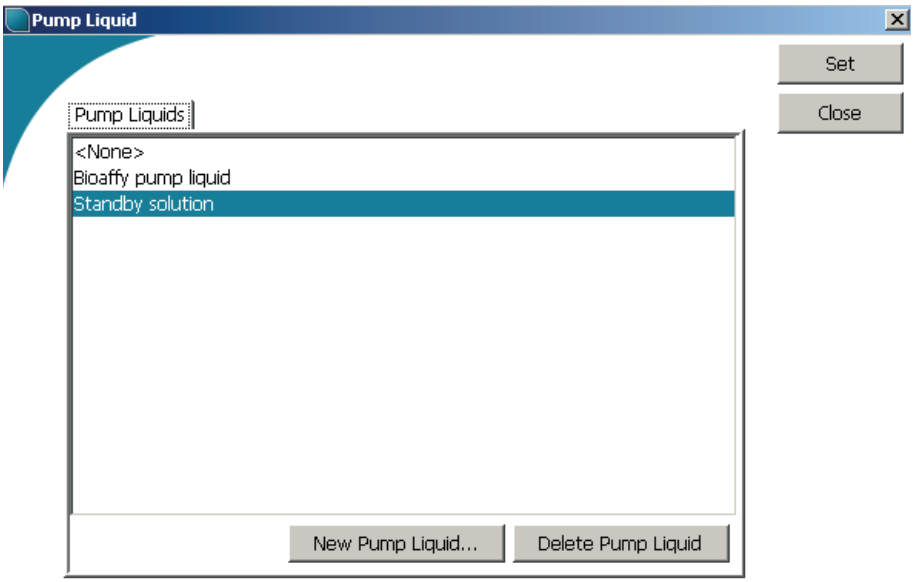


Figure 2: Example of syringe pump configuration tab

Step	Action
1.	Indicate the role of the syringe pump by marking one or both of the check boxes, **Samples** and **Reagents**, for each pump.
2.	Enter the **Syringe Volume** in µl.
3.	Enter the **Connected Needles**, if not already completed.
4.	In the General Pump Settings section, enter **Pump to Needle Prime Volume** in µl. The Pump to Needle Prime Volume is the volume used to rinse the tubing between the syringe pump and its connected needles during priming.
5.	In the General Pump Settings section, enter **Bottle to Pump Prime Volume** in µl. The Bottle to Pump prime Volume is the volume used to rinse the tubing between the pump liquid bottle and the syringe pump during priming.
6.	Enter the **Minimum Needle Volume** in µl.
7.	Enter the **Maximum Needle Volume** in µl.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
8.	Click **Standby Liquid.** The standby liquid is the solution used to put the system in Standby mode. The **Pump Liquids** dialog displays a list of available liquids:



9.	Select Standby Solution by clicking its name in the list. • To add new liquids to the list, click **New Pump Liquid** Type a new name and click **OK**. • To remove a liquid from the list, select a name in the list and click **Delete Pump Liquid** and click **OK** to confirm deletion.
10.	Click **Set**. The standby liquid appears on the tab.
11.	Click **Save** to save syringe pump settings.

Configure Wash Stations

The system is equipped with two wash station pumps, one for each Wash Station. The wash station pumps are primed with wash station solutions.

The two Wash Stations are configured on the **Wash Stations** tab in the **Configure System** screen.

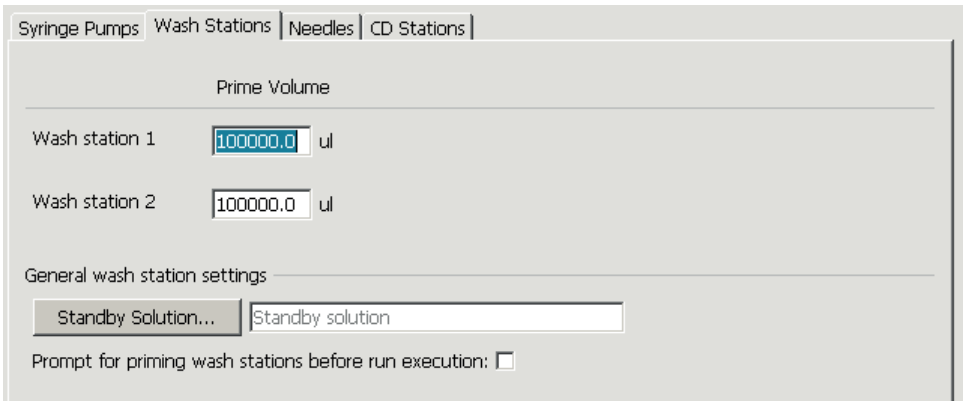
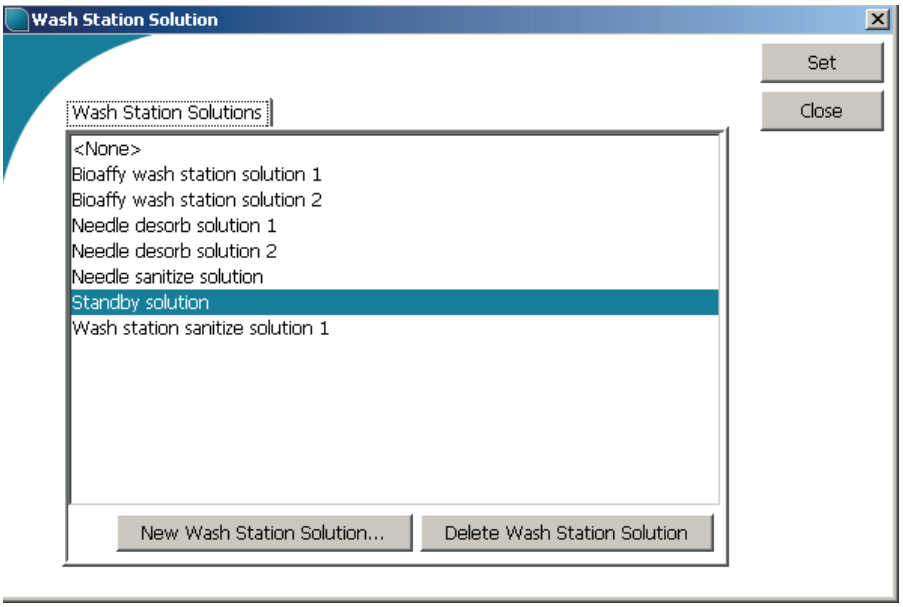


Figure 3: Example of Wash Station configuration tab

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
1.	Enter the **Prime Volume** in µl for Wash Stations 1 and 2. The Prime Volume is the volume used to rinse the tubing between the wash station bottle and the Wash Station during priming.
2.	Click **Standby Solution** at the bottom of the tab. The standby liquid is the solution used to put the system in Standby mode. The **Wash Station Solution** dialog is displayed containing a list of available standby solutions.



3.	Select the Standby Solution to be added by clicking its name in the list. • To add new liquids to the list, click **New Wash Station Solution** Type a new name and click **OK**. • To remove a standby liquid from the list, select a name in the list and click **Delete Wash Station Solution**. • Click **OK** to confirm deletion.
4.	Click **Set**. The Standby Solution appears on the tab.
5.	Click **Save** to save wash station settings.

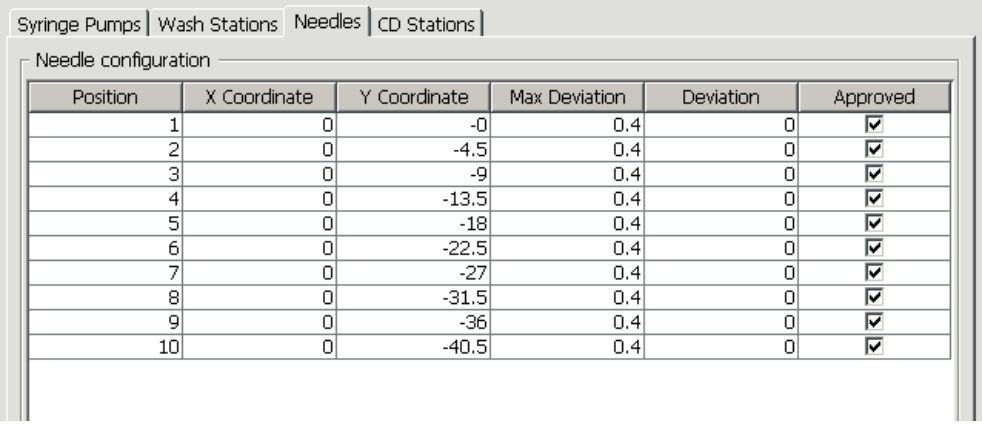
Align needles

An alignment procedure can be performed to ensure that the needles are correctly aligned (i.e. on target for the wells of a microplate). This procedure is normally only performed by Gyros Service staff when needles have been replaced.

The alignment procedure is controlled from the **Needles** tab on the **Configure System** screen. The tab holds a list of the needles along with their nominal positions and the allowed deviation ranges.

NOTE: ***The nominal positions and allowed deviation ranges are set by the manufacturer and cannot be altered.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A



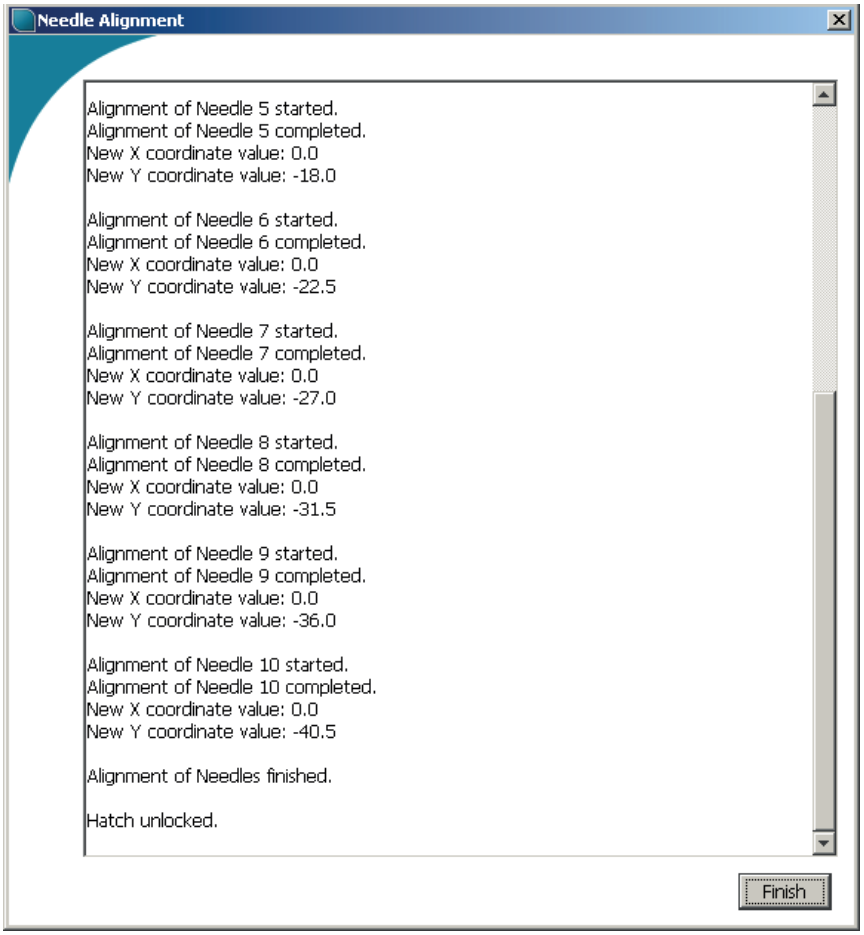
Position	X Coordinate	Y Coordinate	Max Deviation	Deviation	Approved
1	0	-0	0.4	0	☑
2	0	-4.5	0.4	0	☑
3	0	-9	0.4	0	☑
4	0	-13.5	0.4	0	☑
5	0	-18	0.4	0	☑
6	0	-22.5	0.4	0	☑
7	0	-27	0.4	0	☑
8	0	-31.5	0.4	0	☑
9	0	-36	0.4	0	☑
10	0	-40.5	0.4	0	☑

Figure 4: Needles tab

Step Action

1. Click **Align**

The **Aligning Needles** dialog box is displayed:


Needle Alignment
Alignment of Needle 5 started.
Alignment of Needle 5 completed.
New X coordinate value: 0.0
New Y coordinate value: -18.0
Alignment of Needle 6 started.
Alignment of Needle 6 completed.
New X coordinate value: 0.0
New Y coordinate value: -22.5
Alignment of Needle 7 started.
Alignment of Needle 7 completed.
New X coordinate value: 0.0
New Y coordinate value: -27.0
Alignment of Needle 8 started.
Alignment of Needle 8 completed.
New X coordinate value: 0.0
New Y coordinate value: -31.5
Alignment of Needle 9 started.
Alignment of Needle 9 completed.
New X coordinate value: 0.0
New Y coordinate value: -36.0
Alignment of Needle 10 started.
Alignment of Needle 10 completed.
New X coordinate value: 0.0
New Y coordinate value: -40.5
Alignment of Needles finished.
Hatch unlocked.
Finish

2. Click **Finish**.

If the alignment process fails repeatedly, please contact your local Gyros office (refer to www.gyros.com for contact details).

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Configure CD stations

The CD stations tab displays how each of the CD stations is configured. These settings cannot be changed.

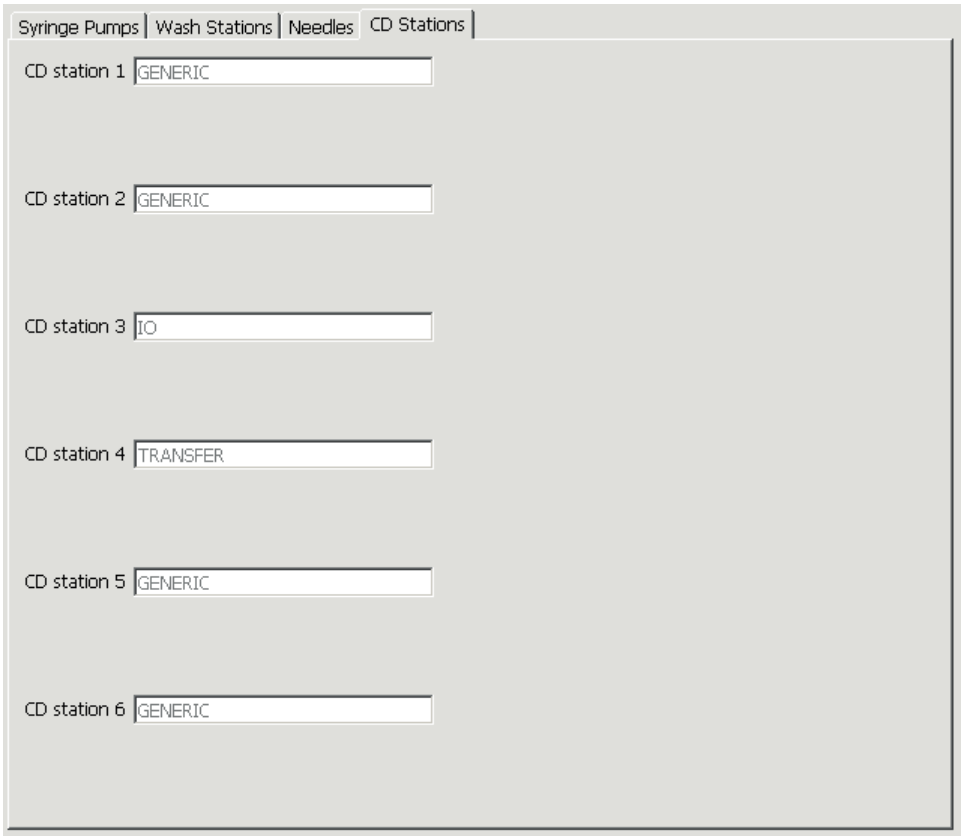
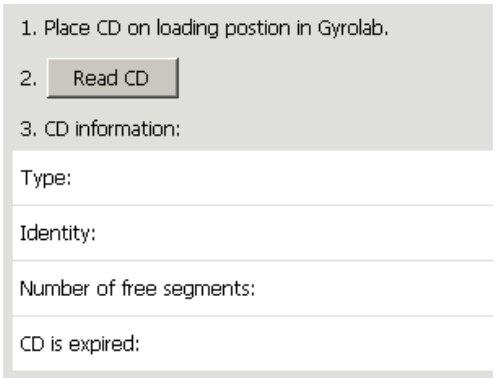


Figure 5: CD stations tab

F1.1.3.8 CD information

CD Information is used to read the information stored in the CD tag.

Step	Action
1.	Click CD information. The CD information screen opens.



2.	Place CD of interest in the instrument CD loading position, refer to Chapter A2.2.1.

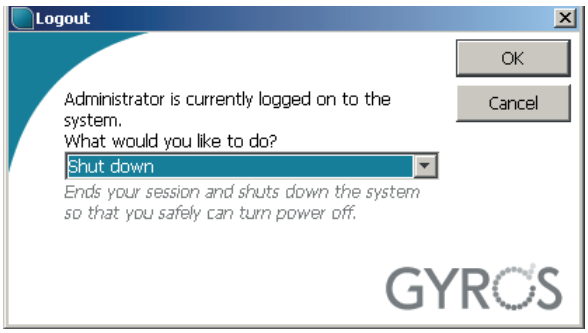
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
3.	Click **Read CD**. The following information of the CD is given: • **Type**: type of CD. • **Identity**: identification number of CD. • **Number of free segments**: number of unused segments on the CD. • **CD is expired**: Do not use the CD if the CD is expired.
4.	Remove the CD from the Gyrolab instrument.
5.	Click **Close** to close the CD information screen.

F1.1.3.9 Logout

Logout is used for shut down, log off or restart of Gyrolab Control:

Step	Action
1.	Click **Logout**. The **Logout** dialog opens.


Logout
OK
Cancel
Administrator is currently logged on to the system.
What would you like to do?
Shut down
Ends your session and shuts down the system so that you safely can turn power off.
GYROS

2.	Select desired function (**Shut down, Log off** or **Restart**) and click **OK**.
3.	Gyrolab Control performs desired function. Additional windows may open. Select desired function and click **OK** to complete **Shut down, Log off** or **Restart**.

F1.1.3.10 Help

To access the help section (a pdf version of Gyrolab User Guide), click **Help** on the main menu and browse for needed Gyrolab User Guide chapter.

F1.1.3.11 About

Click **About** to get information about the software versions and licences for Gyrolab Control.

F1.1.3.12 View Alarm

Gyrolab Control has a built-in warning system. A traffic light icon in the bottom left hand side of the main menu indicates alarm state.

Figure 6: Alarm LEDs

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Alarms

LED	Level	Requires action
Green	No active alarm	No.
Yellow	Warning alarm	Optional. A warning means that the system cannot operate according to configuration set-up. A warning does not affect the physical ability of the Gyrolab instrument, but may have an impact on the results.
Red	Normal alarm	Yes. This alarm indicates an error in the physical operation of the Gyrolab instrument. The instrument will either complete a specific operation or pause immediately. It should be possible to resolve the problem and continue with the system in operating mode.
Red flashing	Critical alarm	Yes. This alarm indicates an error in the physical operation of the Gyrolab instrument. The instrument will either complete a specific operation or pause immediately. The problem must be resolved and the system must be re-initialized.

View information on individual alarms

- To display information on current active alarms, click **View Alarm** on the main menu.
- To view detailed information for a specific alarm, select the alarm in the list. The additional information is displayed in the box below the list.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

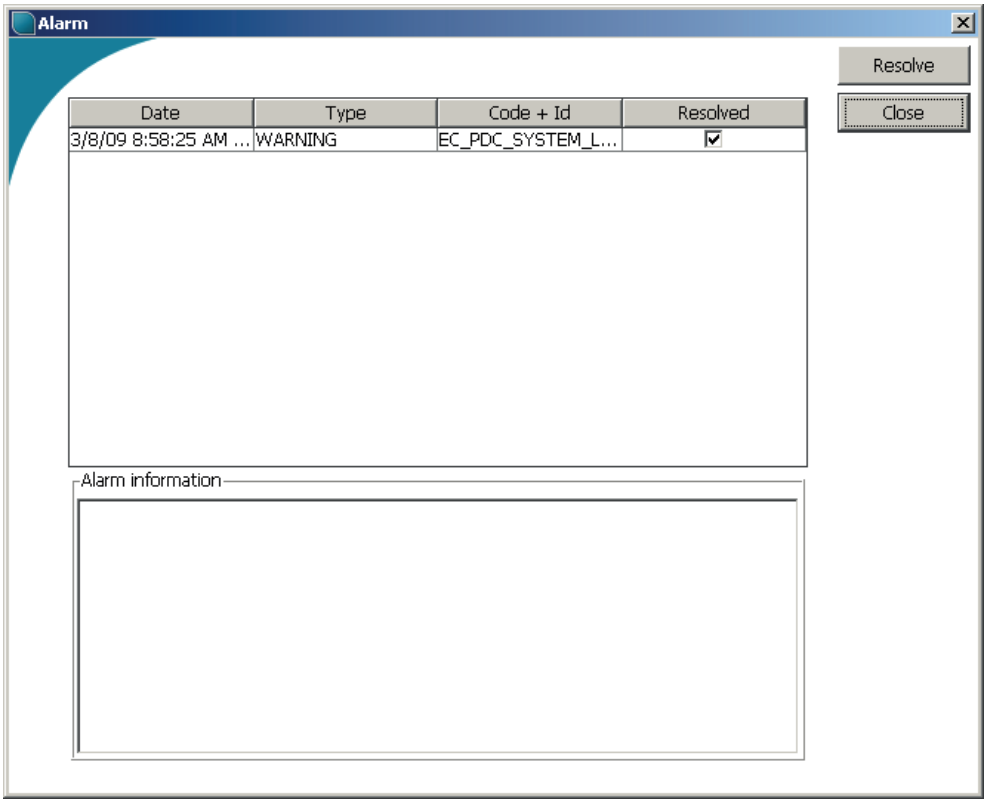


Figure 7: View alarm information

When an alarm occurs, a dialog box is displayed in which the alarm can be confirmed and the **View Alarm** dialog can be accessed.

NOTE: All Normal (red) and Critical (red flashing) alarms must be confirmed.

Address the issue displayed in the **View Alarm** dialog and click **Resolve**.

F1.1.3.13 Instrument access

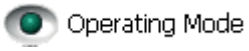
Instrument access status is indicated by a green LED below the function buttons on the main screen.

When the instrument access LED is lit, the main power is on and the connection between instrument and computer is functioning.

NOTE: Even if the instrument access LED is not lit (indicating no instrument access), methods and Runs can still be created and edited.

F1.1.3.14 Instrument modes

Instrument mode is indicated by a LED below the instrument access LED (refer to Chapter F1.1.3.13) in the main menu.



Instrument mode and user privileges (refer to Chapter F2.2.6) determine what functions are available in the main menu.

The change of instrument mode is triggered by actions from the user or the control software. These actions differ depending on the status of the Gyrolab instrument.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Gyrolab instrument modes:

Mode	Description	LED appearance	Accessible from	Activated by
Power off	Gyrolab Control software is started. System is ready to be initialized.	Off	• Initializing • Standby • Operating	• Initialization failure • User log out • Switching off the Gyrolab instrument • Critical alarms
Initializing	Hardware tests are being performed.	Not indicated by LED	• Power off	• User selects **Initialize System...** and follows the directions on the screen.
Operating	System is ready for use.	On	• Initializing • Standby	• Successful initialization • Starting a Run • Priming the system
Standby	System has been primed with standby solutions.	Flashing	• Operating	• Operator selects **Standby** and follows the directions on the screen.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F1.2 Instructions for Gyrolab xPlore

F1.2.1 Start Gyrolab Control

The control software consists of the server and the client. The server must be running before starting the client.

Step	Action

1. Start Gyrolab Server:

- Click **Start:All Programs:Gyros:Server**.
- **Gyrolab Instrument Log** is displayed and Gyrolab server icon appears on the task bar.

2. Start Gyrolab Control software:

- Select **Start:All Programs:Gyros:Client**.

3. The **Login** dialog box is displayed. Enter user name and password in the **Login** dialog box.

NOTE: ***User name and password are case sensitive.***

NOTE: ***The software will request the user to log in anew when the system has been inactive for 31 minutes.***

4. Password must be changed when requested by Gyrolab Control. Password may also be changed when desired by a user:

he **Change Password** window opens:

- Enter present **Password**.
- Enter **New Password**.
- **Confirm Password**.
- Click **OK**.

5. Click **OK** to log in or **Exit** to close the dialog box without logging in. Once logged in, the main menu will appear.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F1.2.2 Gyrolab Control main menu

F1.2.2.1 Main menu overview

The start screen in Gyrolab Control holds the main menu from which all actions are initiated. The main menu also displays instrument access status (refer to Chapter F1.1.3), instrument mode (refer to Chapter F1.1.3.14) and functionality for alarm handling.

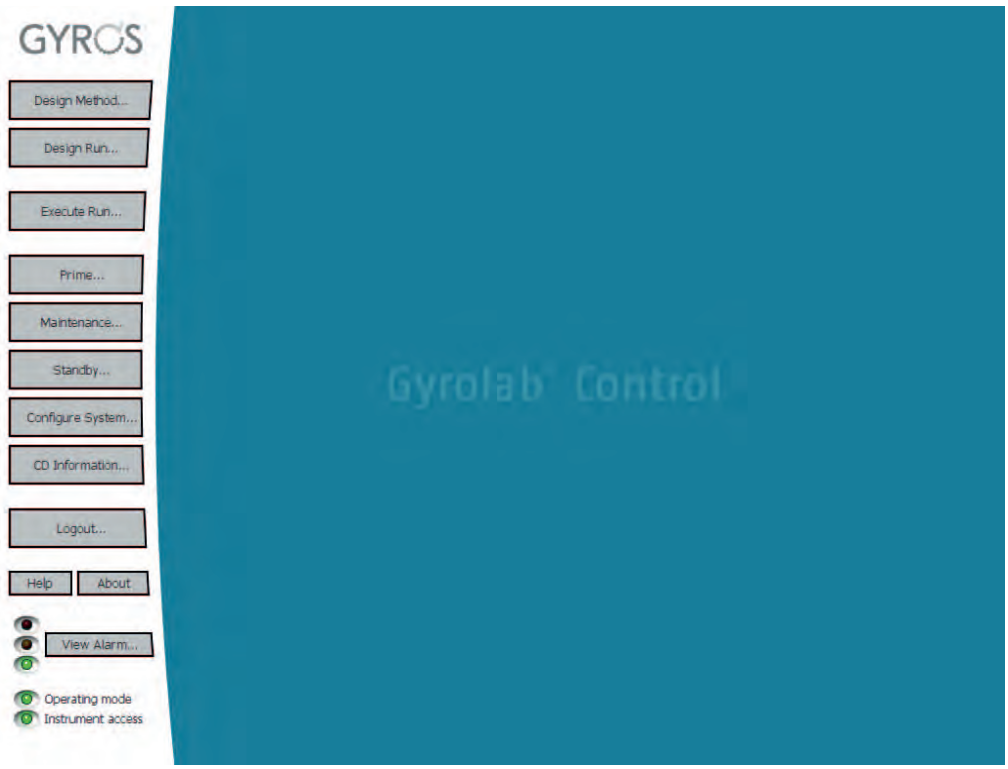


Figure 8: Main menu

The main functions of Gyrolab Control are represented by buttons on the main menu. Only one function at a time can be activated. Select a function by clicking on the function button and the panel for the selected function is displayed on the screen.

Buttons may be accessible (in the example above: **Initialize System**), inaccessible (in the example above: **Prime** button) or hidden (in the example above: **Execute Run** button).

F1.2.3 Main menu functions

Button/LED	Function
Design Method	Launches the **Design Method** screen to create new methods/edit method, refer to Chapter F1.2.3.1.
Design Run	Launches the **Design Run** screen to create new/edit/delete Runs, refer to Chapter F1.2.3.2
Execute Run	Launches the **Execute Run** screen to prepare and start a Run, Chapter F1.2.3.3
Prime	Launches the **Prime** screen to set priming parameters perform instrument priming, refer to Chapter F1.2.3.4

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Button/LED	Function
Maintenance	Launches the **Maintenance** screen to perform instrument priming and/or a cleaning method, refer to Chapter F1.2.3.5
Initialize System	Starts system initialization, refer to Chapter F1.2.3.6
Configure System	Launches the **Configure System** screen to change the system configuration, refer to Chapter F1.2.3.7
CD Information	Launches functionality to read information from a CD tag.
Logout	**Logout** from Gyrolab Control.
Help	Launches the help system, refer to Chapter F1.2.3.10
About	Displays information on software versions and licences, refer to Chapter F1.2.3.11
View Alarm	Displays information about alarms, refer to Chapter F1.2.3.12
Instrument access LED	Indicates instrument access status, refer to Chapter F1.2.3.13
Instrument mode LED	Indicates instrument mode, refer to Chapter F1.2.3.14

F1.2.3.1 Design Method

Design Method function is used for setting up new or edit existing Methods to be used in Runs. Methods can be customized by Gyros to suit specific needs. Contact Gyros for more information.

F1.2.3.2 Design Run

The information required to perform an immunoassay on the Gyrolab instrument is collected in a **Run**. The function **Design Run** is used to create, edit, and delete Runs. Input data for a Run differs depending on which design type (which type of Run) is used.

- For a detailed description of how to create or edit Wizard Runs, refer to Chapter B3.2.2.
- For a detailed description of how to create or edit LIMS Runs, refer to Chapter B3.2.5.

F1.2.3.3 Execute Run

Runs are prepared, loaded, executed, unloaded and finished in the **Execute Run** function. The run design is completed with sample information (Sample List) and settings for result and report files. Input data and settings differs depending on which design type (which type of Run) is used.

- For a detailed description of how to prepare and execute Wizard Runs, refer to Chapter B3.2.4.
- For a detailed description of how to prepare and execute LIMS Runs, refer to Chapter D3.
- For a detailed description of how to prepare and execute Custom Runs, refer to Chapter B3.2.4.

F1.2.3.4 Prime

Instrument priming is performed through this function. Refer to Gyrolab Instrument Guide.

F1.2.3.5 Maintenance

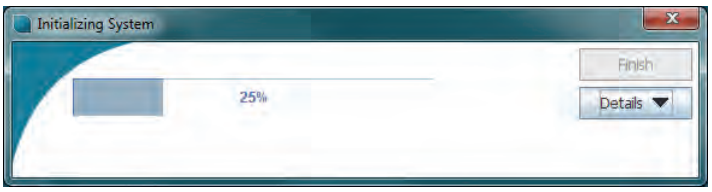
Maintenance function is used for system maintenance. Refer to Gyrolab Instrument Guide for information about specific methods and procedures.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F1.2.3.6 Initialize System

Hardware tests of the components are performed during initialization, for example robot arm movements, carousel rotation and vacuum of the CD stations.

Step	Action
1.	Close the Gyrolab instrument hatch if open. Click **Initialize System** on the Main menu. The **Initializing System** dialog box is displayed as initialization proceeds.



Details of the initialization can be viewed by clicking on the **Details** button.

NOTE: ***To re-initialize the system, click on Logout in the Main menu. Choose Restart from the drop down menu in the Shut Down dialog, then click OK.***

2.	Click **Finish** when initialization is complete.

F1.2.3.7 Configure System

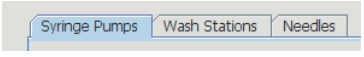
The Gyrolab instrument is delivered with a pre-programmed configuration set-up and system priming protocol. This section explains how to configure the system and alter these settings.

CAUTION: Contact Gyros before changing any configuration default settings.

NOTE: ***Only user with user levels Method Developer or System Administrator can configure the system, refer to Chapter F2.2.6.***

Access the Configure System screen

Step	Action
1.	If the instrument is not initialized, click **Initialize** on the main menu. ***NOTE:*** ***The system must be initialized in order to access the Configure System screen.***
2.	Click the **Configure System** button on the main menu.
3.	Select desired tab, refer to chapters "Configure Syringe Pumps" on page 22 to "Align needles" on page 24 for further instructions.



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Configure Syringe Pumps

The system is equipped with five Syringe Pumps that control two needles each. Pump number 1 controls needles 1 and 2, pump number 2 controls needles 3 and 4 and so on. This set-up is displayed on the **Syringe Pumps** tab in the **Configure System** screen.

NOTE: Different Syringe Pumps can handle different liquids.

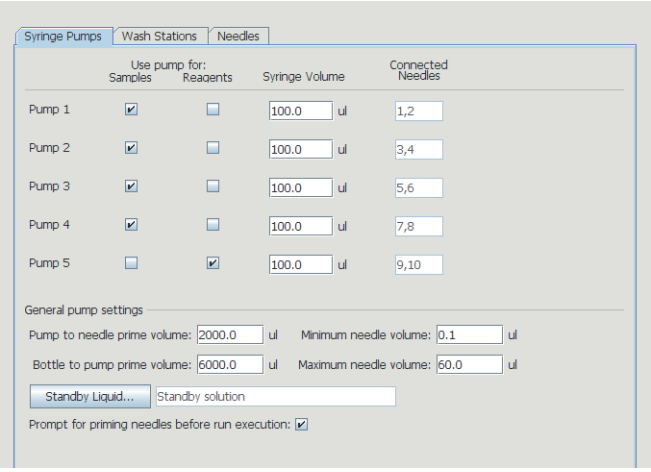
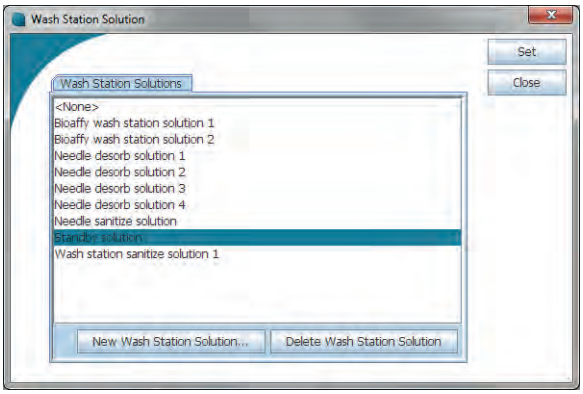


Figure 9: Example of syringe pump configuration tab

Step	Action
1.	Indicate the role of the syringe pump by marking one or both of the check boxes, **Samples** and **Reagents**, for each pump.
2.	Enter the **Syringe Volume** in µl.
3.	Enter the **Connected Needles**, if not already completed.
4.	In the General Pump Settings section, enter **Pump to Needle Prime Volume** in µl. The Pump to Needle Prime Volume is the volume used to rinse the tubing between the syringe pump and its connected needles during priming.
5.	In the General Pump Settings section, enter **Bottle to Pump Prime Volume** in µl. The Bottle to Pump prime Volume is the volume used to rinse the tubing between the pump liquid bottle and the syringe pump during priming.
6.	Enter the **Minimum Needle Volume** in µl.
7.	Enter the **Maximum Needle Volume** in µl.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
8.	Click **Standby Liquid.** The standby liquid is the solution used to put the system in Standby mode. The **Pump Liquids** dialog displays a list of available liquids:



9.	Select Standby Solution by clicking its name in the list. • To add new liquids to the list, click **New Pump Liquid** Type a new name and click **OK**. • To remove a liquid from the list, select a name in the list and click **Delete Pump Liquid** and click **OK** to confirm deletion.
10.	Click **Set**. The standby liquid appears on the tab.
11.	Click **Save** to save syringe pump settings.

Configure Wash Stations

The system is equipped with two wash station pumps, one for each Wash Station. The wash station pumps are primed with wash station solutions.

The two Wash Stations are configured on the **Wash Stations** tab in the **Configure System** screen.

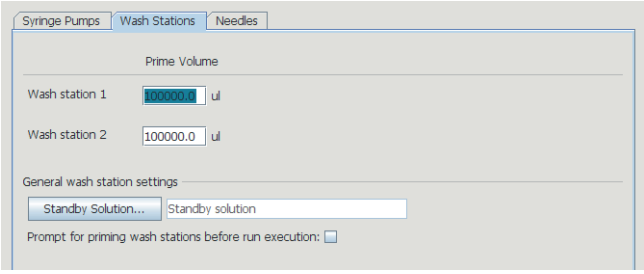
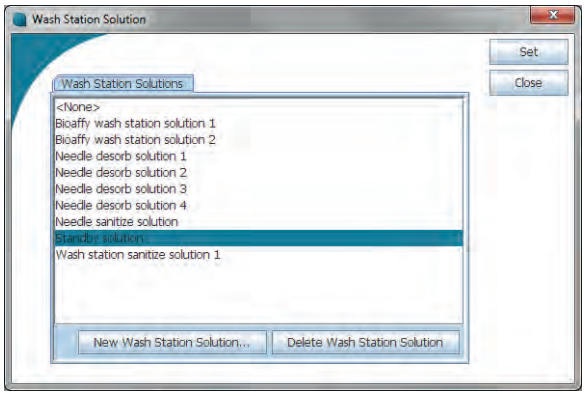


Figure 10: Example of Wash Station configuration tab

Step	Action
1.	Enter the **Prime Volume** in µl for Wash Stations 1 and 2. The Prime Volume is the volume used to rinse the tubing between the wash station bottle and the Wash Station during priming.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
2.	Click **Standby Solution** at the bottom of the tab. The standby liquid is the solution used to put the system in Standby mode. The **Wash Station Solution** dialog is displayed containing a list of available standby solutions.



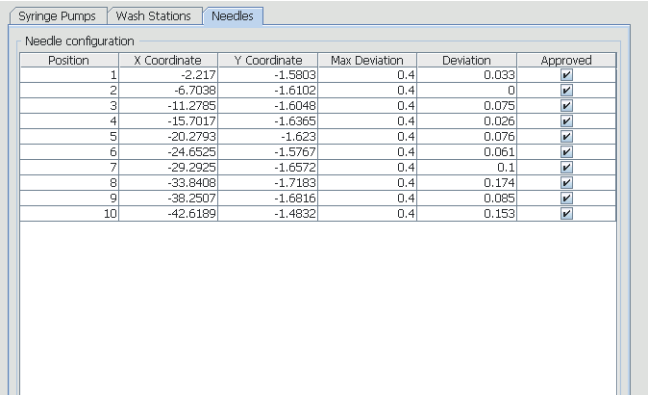
3.	Select the Standby Solution to be added by clicking its name in the list. • To add new liquids to the list, click **New Wash Station Solution** Type a new name and click **OK**. • To remove a standby liquid from the list, select a name in the list and click **Delete Wash Station Solution**. • Click **OK** to confirm deletion.
4.	Click **Set**. The Standby Solution appears on the tab.
5.	Click **Save** to save wash station settings.

Align needles

An alignment procedure can be performed to ensure that the needles are correctly aligned (i.e. on target for the wells of a microplate). This procedure is normally only performed by Gyros Service staff when needles have been replaced.

The alignment procedure is controlled from the **Needles** tab on the **Configure System** screen. The tab holds a list of the needles along with their nominal positions and the allowed deviation ranges.

NOTE: ***The nominal positions and allowed deviation ranges are set by the manufacturer and cannot be altered.***

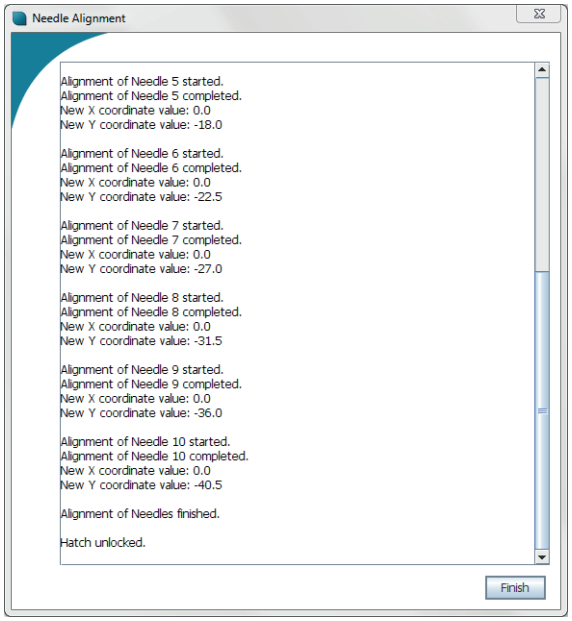


Position	X Coordinate	Y Coordinate	Max Deviation	Deviation	Approved
1	-2.217	-1.5803	0.4	0.033	☑
2	-6.7038	-1.6102	0.4	0	☑
3	-11.2785	-1.6048	0.4	0.075	☑
4	-15.7017	-1.6365	0.4	0.026	☑
5	-20.2793	-1.623	0.4	0.076	☑
6	-24.6525	-1.5767	0.4	0.061	☑
7	-29.2925	-1.6572	0.4	0.1	☑
8	-33.8408	-1.7183	0.4	0.174	☑
9	-38.2507	-1.6816	0.4	0.085	☑
10	-42.6189	-1.4832	0.4	0.153	☑

Figure 11: Needles tab

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
1.	Click **Align** The **Aligning Needles** dialog box is displayed:

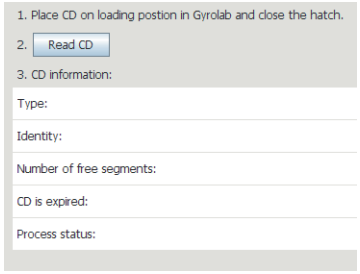

Needle Alignment
Alignment of Needle 5 started.
Alignment of Needle 5 completed.
New X coordinate value: 0.0
New Y coordinate value: -18.0
Alignment of Needle 6 started.
Alignment of Needle 6 completed.
New X coordinate value: 0.0
New Y coordinate value: -22.5
Alignment of Needle 7 started.
Alignment of Needle 7 completed.
New X coordinate value: 0.0
New Y coordinate value: -27.0
Alignment of Needle 8 started.
Alignment of Needle 8 completed.
New X coordinate value: 0.0
New Y coordinate value: -31.5
Alignment of Needle 9 started.
Alignment of Needle 9 completed.
New X coordinate value: 0.0
New Y coordinate value: -36.0
Alignment of Needle 10 started.
Alignment of Needle 10 completed.
New X coordinate value: 0.0
New Y coordinate value: -40.5
Alignment of Needles finished.
Hatch unlocked.
Finish

2.	Click **Finish**. If the alignment process fails repeatedly, please contact your local Gyros office (refer to www.gyros.com for contact details).

F1.2.3.8 CD information

CD Information is used to read the information stored in the CD tag.

Step	Action
1.	Click CD information. The CD information screen opens.



2.	Place CD of interest in the instrument CD loading position and close the hatch, refer to Chapter A2.2.2.

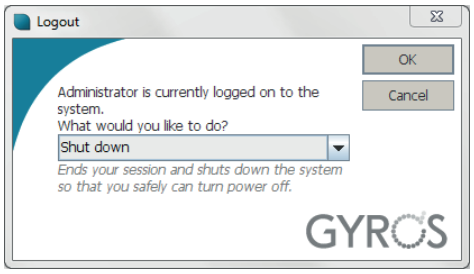
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
3.	Click **Read CD**. The following information of the CD is given: • **Type**: type of CD. • **Identity**: identification number of CD. • **Number of free segments**: number of unused segments on the CD. • **CD is expired**: Do not use the CD if the CD is expired. • **Process status**: Do not use the CD if the status is Unknown
4.	Open the hatch and remove the CD from the Gyrolab instrument.
5.	Click **Close** to close the CD information screen.

F1.2.3.9 Logout

Logout is used for shut down, log off or restart of Gyrolab Control:

Step	Action
1.	Click **Logout**. The **Logout** dialog opens.


Logout
OK
Cancel
Administrator is currently logged on to the system.
What would you like to do?
Shut down
Ends your session and shuts down the system so that you safely can turn power off.
GYROS

2.	Select desired function (**Shut down, Log off** or **Restart**) and click **OK**.
3.	Gyrolab Control performs desired function. Additional windows may open. Select desired function and click **OK** to complete **Shut down, Log off** or **Restart**.

F1.2.3.10 Help

To access the help section (a pdf version of Gyrolab User Guide), click **Help** on the main menu and browse for needed Gyrolab User Guide chapter.

F1.2.3.11 About

Click **About** to get information about the software versions and licences for Gyrolab Control.

F1.2.3.12 View Alarm

Gyrolab Control has a built-in warning system. A traffic light icon in the bottom left hand side of the main menu indicates alarm state.

Figure 12: Alarm LEDs

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Alarms

LED	Level	Requires action
Green	No active alarm	No.
Yellow	Warning alarm	Optional. A warning means that the system cannot operate according to configuration set-up. A warning does not affect the physical ability of the Gyrolab instrument, but may have an impact on the results.
Red	Normal alarm	Yes. This alarm indicates an error in the physical operation of the Gyrolab instrument. The instrument will either complete a specific operation or pause immediately. It should be possible to resolve the problem and continue with the system in operating mode.
Red flashing	Critical alarm	Yes. This alarm indicates an error in the physical operation of the Gyrolab instrument. The instrument will either complete a specific operation or pause immediately. The problem must be resolved and the system must be re-initialized.

View information on individual alarms

- To display information on current active alarms, click **View Alarm** on the main menu.
- To view detailed information for a specific alarm, select the alarm in the list. The additional information is displayed in the box below the list.

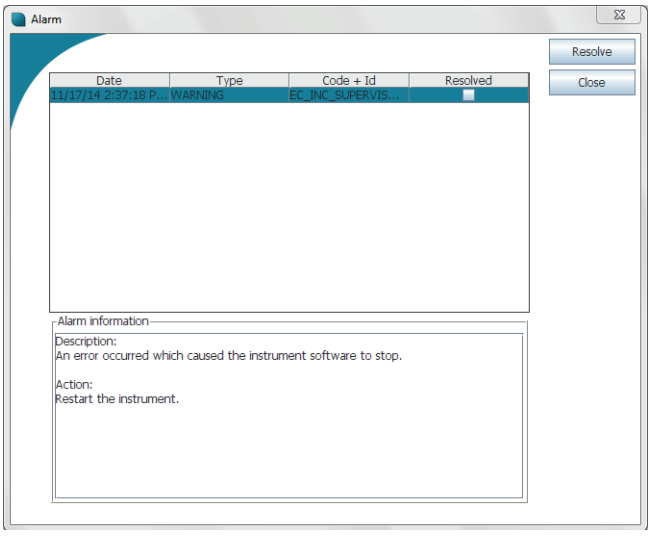


Figure 13: View alarm information

When an alarm occurs, a dialog box is displayed in which the alarm can be confirmed and the **View Alarm** dialog can be accessed.

NOTE: All Normal (red) and Critical (red flashing) alarms must be confirmed.

Address the issue displayed in the **View Alarm** dialog and click **Resolve**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F1.2.3.13 Instrument access

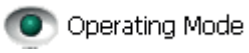
Instrument access status is indicated by a green LED below the function buttons on the main screen.

When the instrument access LED is lit, the main power is on and the connection between instrument and computer is functioning.

NOTE: Even if the instrument access LED is not lit (indicating no instrument access), methods and Runs can still be created and edited.

F1.2.3.14 Instrument modes

Instrument mode is indicated by a LED below the instrument access LED (refer to Chapter F1.1.3.13) in the main menu.



Instrument mode and user privileges (refer to Chapter F2.2.6) determine what functions are available in the main menu.

The change of instrument mode is triggered by actions from the user or the control software. These actions differ depending on the status of the Gyrolab instrument.

Gyrolab instrument modes:

Mode	Description	LED appearance	Accessible from	Activated by
Power off	Gyrolab Control software is started. System is ready to be initialized.	Off	• Initializing • Standby • Operating	• Initialization failure • User log out • Switching off the Gyrolab instrument • Critical alarms
Initializing	Hardware tests are being performed.	Not indicated by LED	• Power off	• User selects **Initialize System...** and follows the directions on the screen.
Operating	System is ready for use.	On	• Initializing • Standby	• Successful initialization • Starting a Run • Priming the system
Standby	System has been primed with standby solutions.	Flashing	• Operating	• Operator selects **Standby** and follows the directions on the screen.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2 Gyrolab Administration Tool

The Administration Tool is used by System Administrators to manage users and various items such as folders, targets, Runs, methods, CD types, microplate types and liquids.

F2.1 Login procedure

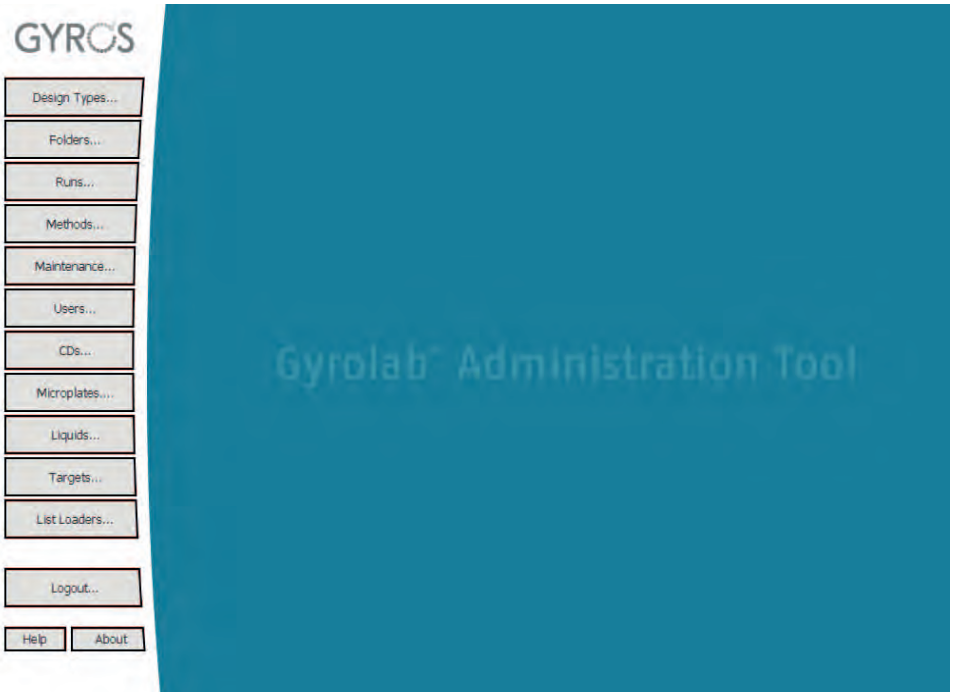
Gyrolab server must be running before the Administration Tool can be started.

Step	Action
1.	Start Gyrolab server: • Click **Start:All Programs:Gyros:Server**. • **Gyrolab Instrument Log** is displayed and Gyrolab server icon appears on the task bar.
2.	Start Gyrolab Administration Tool: Select **Start:All Programs**:**Gyros:Administration Tool**.
3.	Enter user name and password in the **Login** dialog box and click **OK**. The user name and password is the same for all Gyrolab software. For further information on user and password administration, refer to Chapter F2.2.6. Password must be changed if requested by the software, for example when a new user logs in or if 90 days have passed since last password change. Password may also be changed when desired by the user. To change password: • Mark the check-box **Change Password.** • Enter current password in **Password** field, new password in **New Password** field and confirm new password in **Confirm Password** field. • Click **OK**. ***NOTE: User name and password are case sensitive.***
4.	Click **OK** to log in or **Exit** to close the dialog box without logging in. Once logged in, the Administration Tool main menu will appear.
5.	Perform the tasks in Gyrolab Administration Tool according to the descriptions below.
6.	When finished, click the **Logout** button to log out and shut down Gyrolab Administration Tool.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2 Gyrolab Administration Tool main menu

The start screen in Gyrolab Administration Tool holds the main menu from which all main functions are initiated. Only one function at a time can be activated.

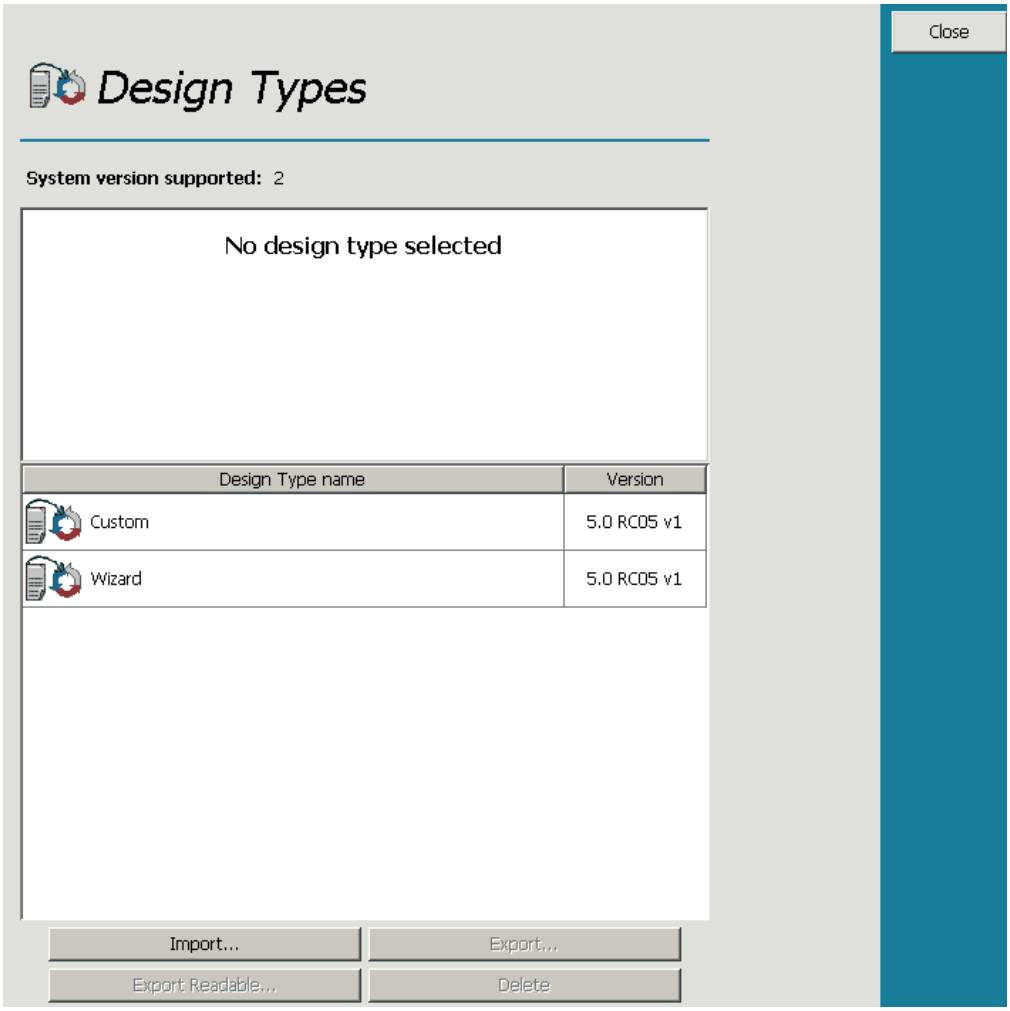


Button	Function
Design types	Manage different Run design types, for example Wizard Run. LIMS Run and Custom Run (import, export, export readable and delete)
Folders	Manage folders (create, edit, cut, paste and delete)
Runs	Manage Runs (import, export, export readable, cut, paste and delete)
Methods	Manage Methods (import, export, export readable, cut, paste and delete)
Maintenance	Manage maintenance methods (import, export, export readable, cut, paste and delete)
Users	Manage users and user permissions (create user, edit user, export user list, audit trail and delete)
CDs	Manage CD types (import, export, export readable and delete)
Microplates	Manage microplate types (import, export, export readable and delete)
Liquids	Manage liquids (import, export, export readable and delete)
Targets	Manage targets used to process Run results (import, export, export readable and delete)
List Loaders	Manage list loader files
Logout	Logs out user from the Administration Tool
Help	Launches the Gyrolab User Guide in pdf format.
About	Provides information of Gyrolab Control version

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.1 Design types

Click on **Design types** on the main menu to access the **Design types** screen. The **Design types** screen lists available design types.



It is possible to perform four different administration tasks: **Import, Export, Export Readable** and **Delete**.

NOTE: Select a design type in the list to activate unavailable task buttons.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

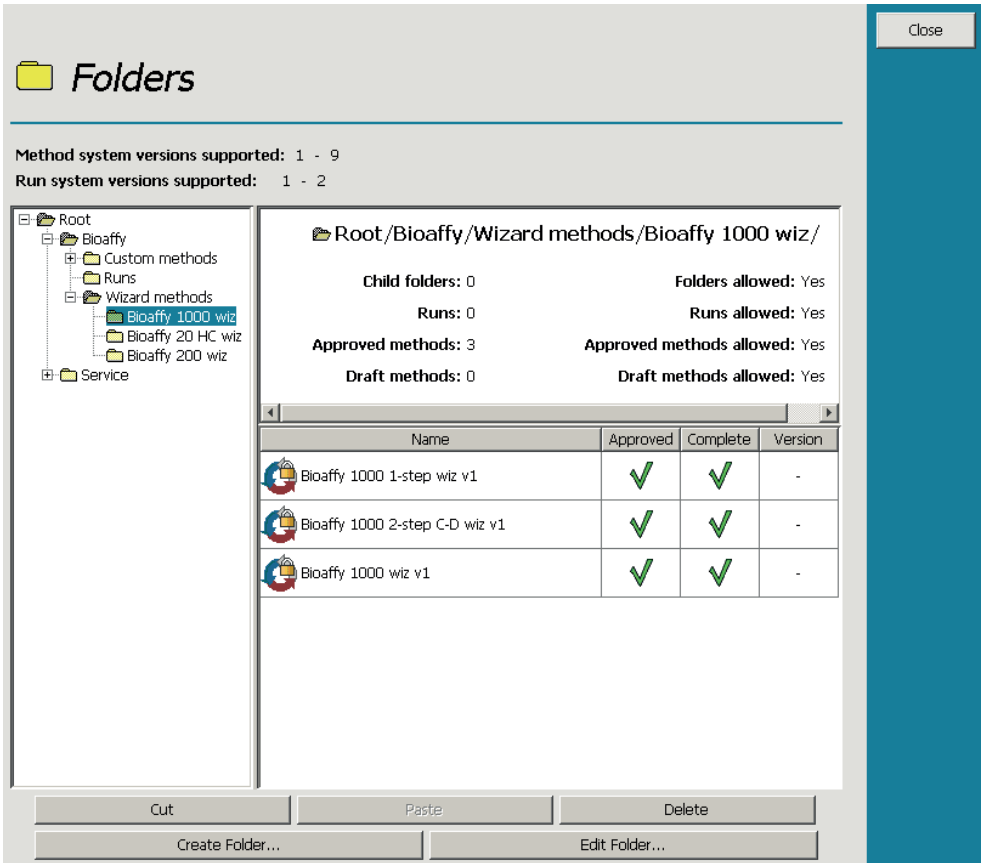
Button	Action
Import	**Import** is used to import design types to Administration Tool to make them available for use in Gyrolab Control. • Click **Import** to open **Import Design type** dialog. • Browse and select desired design type. Design types must be in `.zml` format. • Click **Import**. • Click **OK** in the **Import Design type** dialog to confirm import. The selected design type is now present in the Design type screen list.
Export	**Export** is used to export design types from Administration Tool in order to for example make the design type available for use on another Gyrolab instrument. • Select design type to export. • Click **Export** to open **Export Design type** dialog. • Browse and select desired export folder. • Click **Export**. • Click **OK** in the **Export Design type** dialog to confirm export. The selected design type is now present in the selected export folder.
Export readable	**Export Readable** is used when it is desired to have an uncoded readable copy of a design type. This copy cannot be used in Gyrolab Control but it can be useful when for example contacting Gyros for support. • Select design type to export readable. • Click **Export Readable** to open **Export Design type** in readable format dialog. • Browse and select desired export folder. • Click **Export Readable**. • Click **OK** in the **Export Readable Design type** dialog to confirm export readable. The selected design type is now present in a readable format in the selected export folder.
Delete	**Delete** is used to delete design types. • Select design type to be deleted from **Design type** screen list. • Click **Delete**. • Click **Yes** in the **Delete Design type** dialog to confirm deletion. The selected design type is now removed from the Design type list.

Click **Close** in the top right hand corner of the **Design types** screen to exit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.2 Folders

Click on **Folder** on the main menu to access the **Folders** screen. Select a folder in the folder structure to the left to display its content.



It is possible to perform five different administration tasks: **Cut, Paste, Delete, Create Folder** and **Edit Folder**.

NOTE: Select a folder in the list to activate unavailable task buttons.

Button	Action
Cut and Paste	**Cut** and **Paste** are used to move a folder within the folder structure. • Browse the folder structure to the left in the **Folders** screen to locate folder to be cut. Select folder. • Click **Cut**. • Browse the folder structure to the left in the **Folders** screen to locate a destination folder. Select folder. • Click **Paste**. The folder is now located in its new folder structure position. To paste a folder into another, the destination folder must have status "Allow folder", refer to "Edit folder" on page 34 below.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

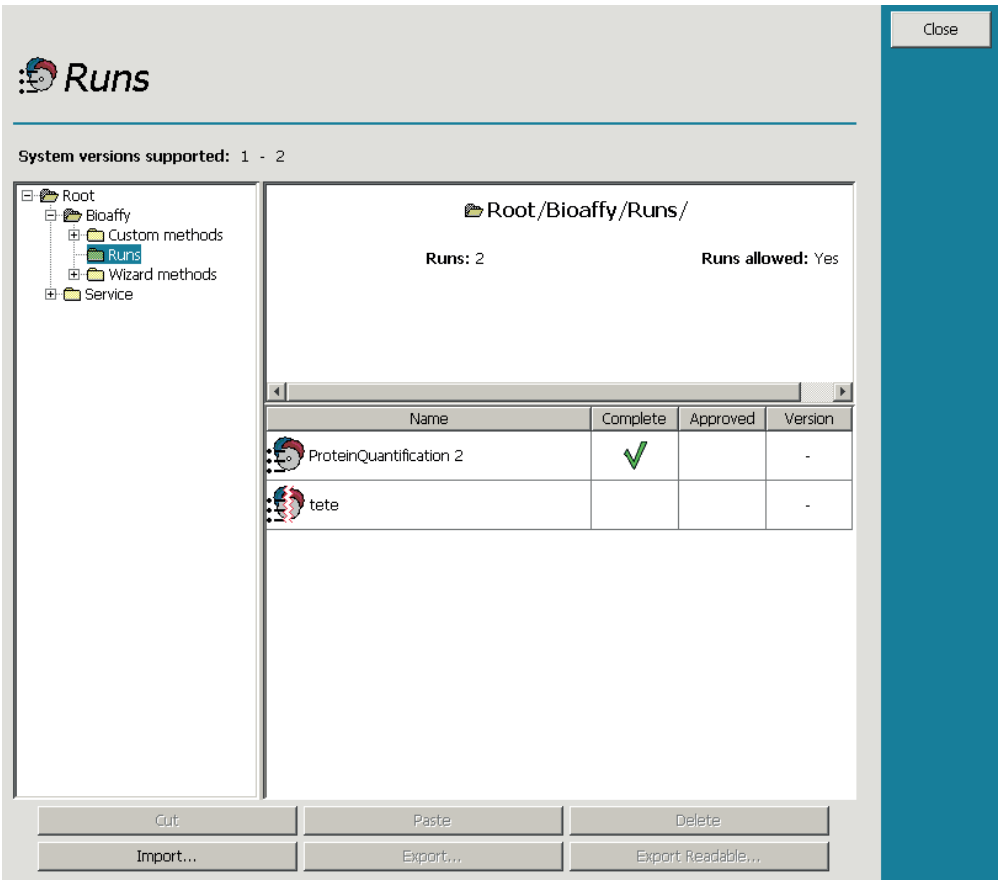
Button	Action
Delete	**Delete** is used to delete folders from the folder structure. • Select folder to be deleted in the folder structure in the left panel of the **Folders** screen. • Click **Delete**. • Click **OK** in the **Delete Folder** dialog to confirm folder deletion. The folder is now removed from the folder structure.
Create folder	**Create folder** is used to create new folders. • Select a parent folder in the folder structure in the left panel of the **Folders** screen. • Click **Create folder**. • In the **Create folder** window, give the new folder a name and set allow or deny status for **Folders, Runs, Draft Methods** and **Approved Methods** for the new folder. • Click **OK** in the **Create Folder** dialog to confirm folder creation. The new folder is now present in its specified folder position within the folder structure.
Edit folder	**Edit folder** is used to change folder name and to change status for allow or deny **Folders, Runs, Draft Methods** and **Approved Methods** in the folder. • Select folder to edit in the folder structure in the left panel of the **Folders** screen. • Click **Edit folder**. • In the **Edit folder** window, change folder name and/or change status for allow or deny **Folders, Runs, Draft Methods** and **Approved Methods** in the folder. • Click **OK**. The folder settings are now updated.

Click on **Close** in the top right hand corner of the **Folders** screen to exit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.3 Runs

Click on **Runs** on the main menu to access the **Runs** screen. Select a folder in the folder structure to display its content.



It is possible to perform six different administration tasks: **Cut, Paste, Delete, Import, Export** and **Export Readable**.

NOTE: Select a run in the list to activate unavailable task buttons.

Button	Action
Cut and Paste	**Cut** and **Paste** are used to move a Run within the folder structure. • Browse the folder structure to the left in the **Runs** screen to locate the folder that holds the Run to be cut. Select folder. • Select Run to be cut in the list to the right in the **Runs** screen. • Click **Cut**. • Browse the folder structure to the left in the **Runs** screen to locate a new folder for the Run. Select folder. • Click **Paste**. The Run is now located in the new folder. ***NOTE: To paste a Run into a folder, the folder must have status "Allow Run", refer to Chapter F2.2.2.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

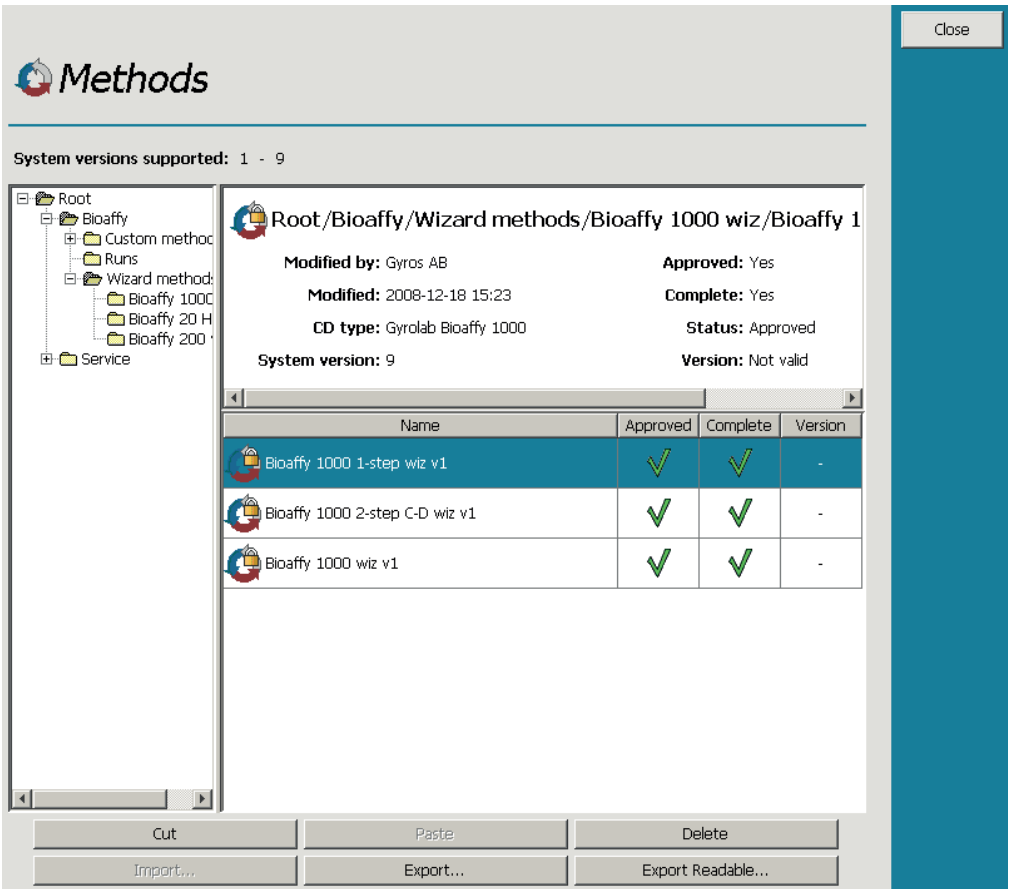
Button	Action
Delete	**Delete** is used to delete a Run. • Browse the folder structure to the left in the **Runs** screen to locate the folder that holds the Run to be deleted. Select folder. • Select the Run to be deleted in the Run list to the right in the **Runs** screen. • Click **Delete**. • Click **OK** in the **Delete Run** dialog to confirm deletion. The selected Run is now deleted from the Runs list.
Import	**Import** is used to import Runs into the Administration Tool to make them available for use in Gyrolab Control. • Browse the folder structure to the left in the **Runs** screen to locate the folder into which the Run is to be imported. Select folder. • Click **Import** to open **Import Runs** dialog. • Browse and select desired Run. Runs must be in `.zml` format. • Click **Import**. • Click **OK** in the **Import Runs** dialog to confirm import. The selected Run is now present in Runs list.
Export	**Export** is used to export Runs from the Administration Tool. Exported Run can be imported into another Gyrolab instrument. • Browse the folder structure to the left in the **Runs** screen to locate the folder that holds the Run to be exported. Select folder. • Select Run to be exported in the Run list to the right in the **Runs** screen. • Click **Export** to open **Export Run** dialog. • Browse and select desired export folder. • Click **Export**. • Click **OK** in the **Export Run** dialog to confirm export. The exported Run is now present in the selected export folder.
Export readable	**Export Readable** is used to export a readable copy of a Run. This copy cannot be used in Gyrolab Control but can be useful for example when contacting Gyros for support. • Browse the folder structure to the left in the **Runs** screen to locate the folder that holds the Run to be exported readable. Select folder. • Select Run to be exported in the Run list to the right in the **Runs** screen. • Click **Export Readable** to open **Export Runs in readable format** dialog. • Browse and select desired export readable folder. • Click **OK** in the **Export Readable Runs** dialog to confirm export readable. The selected Run is now present in a readable format in the selected export folder.

Click on **Close** in the top right hand corner of the **Runs** screen to exit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.4 Methods

Click on **Methods** on the main menu to access the **Methods** screen. Select a folder in the folder structure to display its content.



It is possible to perform six different administration actions: **Cut, Paste, Delete, Import, Export** and **Export Readable**.

NOTE: Select a method in the list to activate inaccessible task buttons.

Button	Action
Cut and Paste	**Cut** and **Paste** are used to move a Method within the folder structure. • Browse the folder structure to the left in the **Methods** screen to locate the folder that holds the Method to be cut. Select folder. • Select Method to be cut in the list to the right in the **Methods** screen. • Click **Cut**. • Browse the folder structure to the left in the **Methods** screen to locate a new folder for the run. • Click **Paste**. The Method is now located in the new folder. ***NOTE: To paste a Method into a folder, the folder must have status "Allow Method", refer to Chapter F2.2.2.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

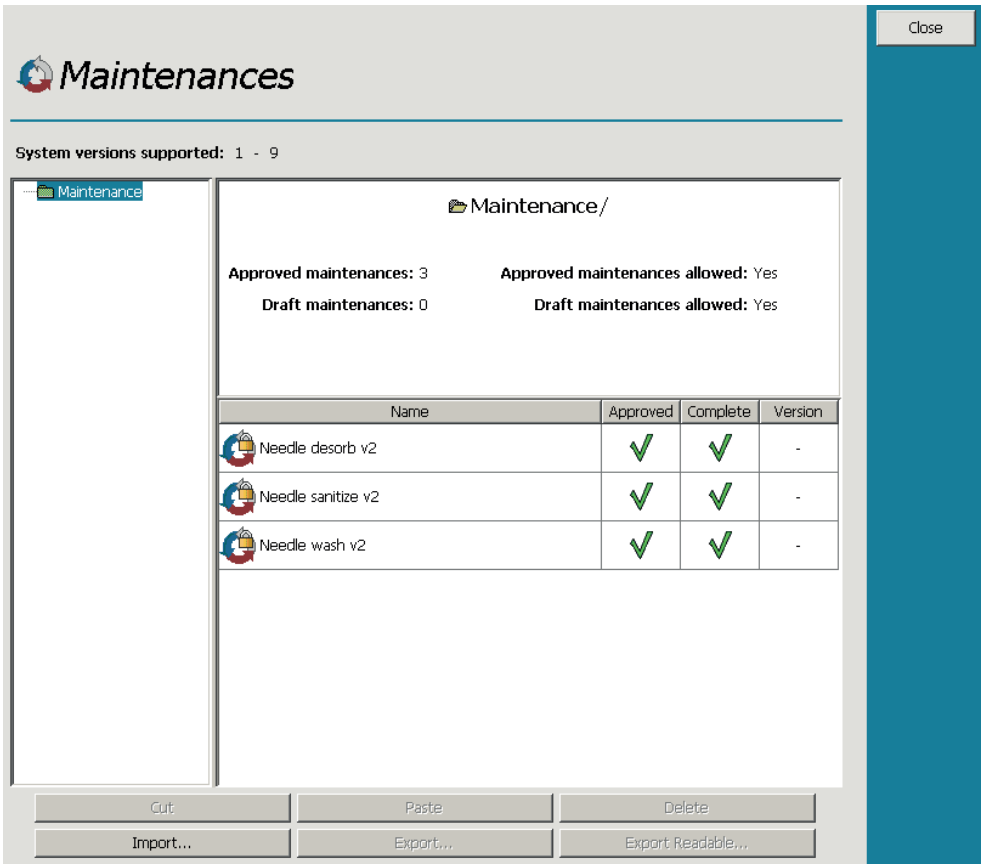
Button	Action
Delete	**Delete** is used to delete a Method. • Browse the folder structure to the left in the **Methods** screen to locate the folder that holds the Method to be deleted. Select folder. • Select the Method to be deleted in the Method list to the right in the **Methods** screen. • Click **Delete**. • Click **OK** in the **Delete Methods** dialog to confirm deletion. The selected Method is now deleted from the Methods list.
Import	**Import** is used to import Methods into the Administration Tool to make them available for use in Gyrolab Control. • Browse the folder structure to the left in the **Methods** screen to locate the folder into which the Method is to be imported. Select folder. • Click **Import** to open **Import Methods** dialog. • Browse and select desired Method. Methods must be in `.zml` format. • Click **Import**. • Click **OK** in the **Import Methods** dialog to confirm import. The selected Method is now present in the Methods list.
Export	**Export** is used to export Methods from the Administration Tool. Exported Method can be imported into another Gyrolab instrument. • Browse the folder structure to the left in the **Methods** screen to locate the folder that holds the Method to be exported. Select folder. • Select Method to be exported in the Method list to the right in the **Methods** screen. • Click **Export** to open **Export Methods** dialog. • Browse and select desired export folder. • Click **Export**. • Click **OK** in the **Export Methods** dialog to confirm export. The selected Method is now present in the selected export folder.
Export readable	**Export Readable** is used to export a readable copy of a Method. This copy cannot be used in Gyrolab Control but it can be useful for example when contacting Gyros for support. • Browse the folder structure to the left in the **Methods** screen to locate the folder that holds the Method to be exported readable. Select folder. • Select Method to be exported in the Method list to the right in the **Methods** screen. • Click **Export Readable** to open **Export Methods in readable format** dialog. • Browse and select desired export readable folder. • Click **OK** in the **Export Readable Methods** dialog to confirm export. The selected Method is now present in a readable format in the selected export folder.

Click on **Close** in the top right hand corner of the **Methods** screen to exit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.5 Maintenance

Click on **Maintenance** on the main menu to access the **Maintenance** screen. Select a folder in the folder structure to display its content.



It is possible to perform six different administration tasks: **Cut, Paste, Delete, Import, Export** and **Export Readable**.

NOTE: Select a maintenance method in the list to activate inaccessible task buttons.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Button	Action
Cut and Paste	**Cut** and **Paste** are used to move a Maintenance method within the folder structure. • Browse the folder structure to the left in the **Maintenance** screen to locate the folder that holds the Maintenance method to be cut. Select folder. • Select Maintenance method to be cut in the list to the right in the **Methods** screen. • Click **Cut**. • Browse the folder structure to the left in the **Maintenance** screen to locate a new folder for the run. • Click **Paste**. The Maintenance method is now located in the new folder. ***NOTE:*** ***To paste a Maintenance method into a folder, the folder must have status "Allow Maintenance method", refer to Chapter F2.2.2.***
Delete	**Delete** is used for to delete a Maintenance method. • Browse the folder structure to the left in the **Maintenance** screen to locate the folder that holds the Maintenance method to be deleted. Select folder. • Select the Maintenance method to be deleted in the Maintenance method list to the right in the **Maintenance** screen. • Click **Delete**. • Click **OK** in the **Delete Maintenance** dialog to confirm deletion. The selected Maintenance method is now deleted from the Maintenance method list.
Import	**Import** is used to import Maintenance methods into Administration Tool to make them available for use in Gyrolab Control. • Browse the folder structure to the left in the **Maintenance** screen to locate the folder into which the Maintenance method is to be imported. Select folder. • Click **Import** to open Import **Maintenance** dialog. • Browse and select desired Maintenance method. Maintenance methods must be in `.zml` format. • Click **Import**. • Click **OK** in the **Import Maintenance** dialog to confirm import. The selected Maintenance method is now present in the Maintenance method list.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Button	Action
Export	**Export** is used to export Maintenance methods from Administration Tool. Exported Maintenance method can be imported into another Gyrolab instrument. • Browse the folder structure to the left panel in the **Maintenance** screen to locate the folder that holds the Maintenance method to be exported. • Select Maintenance method to be exported in the list to the right in the **Maintenance** screen. • Click **Export** to open **Export Maintenance** dialog. • Browse and select desired export folder. • Click **Export**. • Click **OK** in the **Export Maintenance** dialog to confirm export. The selected Maintenance method is now present in the selected export folder.
Export readable	**Export Readable** is used to export a readable copy of a Maintenance method. This copy cannot be used in Gyrolab Control but it can be useful for example when contacting Gyros for support. • Browse the folder structure to the left panel in the **Maintenance** screen to locate the folder that holds the Maintenance method to be exported. • Select Maintenance method to be exported in the list to the right in the **Maintenance** screen. • Click **Export Readable** to open **Export Maintenance in readable format** dialog. • Browse and select desired export readable folder. • Click **OK** in the **Export Readable Maintenance** dialog to confirm export readable. The selected Maintenance method is now present in a readable format in the selected export folder.

Click on **Close** in the top right hand corner of the **Maintenance** screen to exit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.6 Users

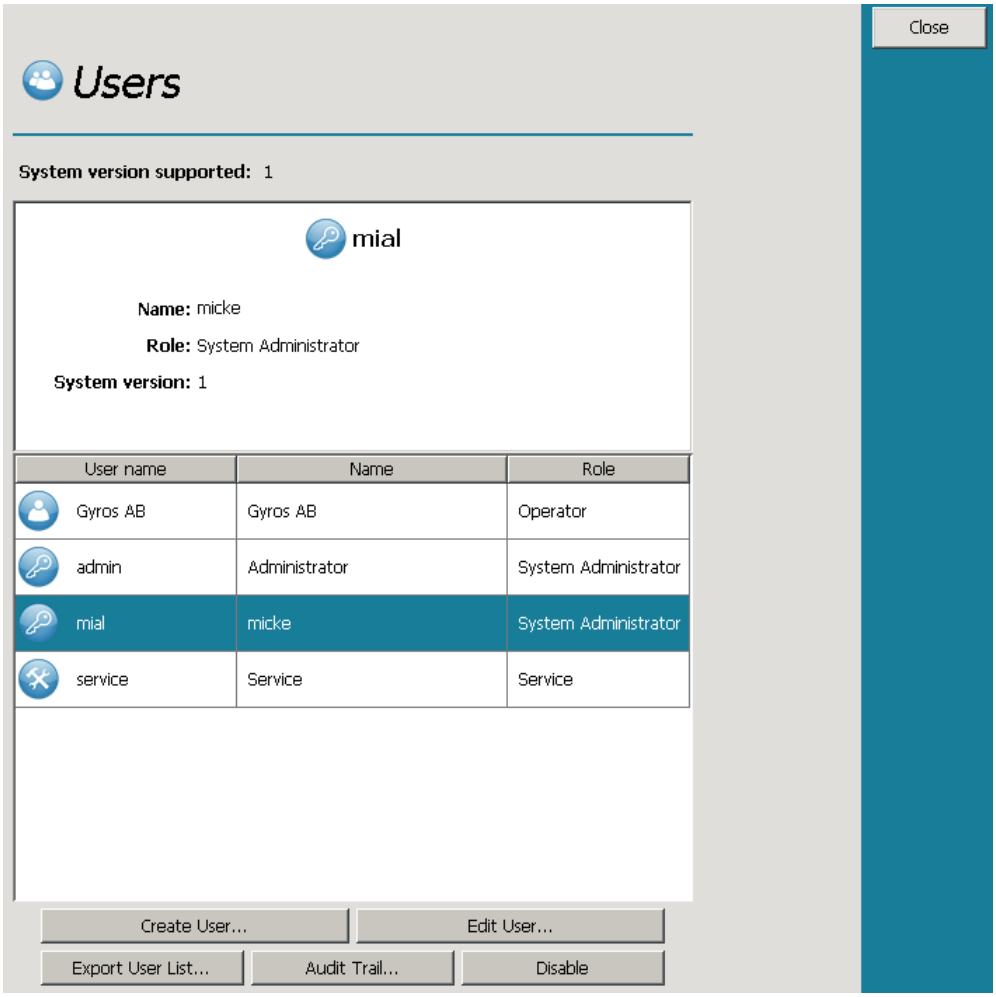
Click on **Users** on the main menu to access the **Users** screen. The **Users** screen lists Gyrolab software users with their user levels. Four different user levels can be assigned to users. There is also a Service user level used by Gyros during services.

Each user level has a defined set of user privileges. A System Administrator is allowed to perform all actions whereas a Operator has more limited user privileges focused on performing Gyrolab experiments. Using different user levels it is possible to control the workflow and give access to critical steps to a limited number of users.

All users log in to Gyrolab software with their user name and a password. The password must be changed the first time a user logs in and then every 90th day.

During introductory customer training Gyros provides temporary **User Name** and **Password** for the computer controlling Gyrolab instrument and for Gyrolab software. This User has user level System Administrator and that user can create and edit other users with different user levels.

NOTE: Service personnel from Gyros must be given access as a local administrator if requested.

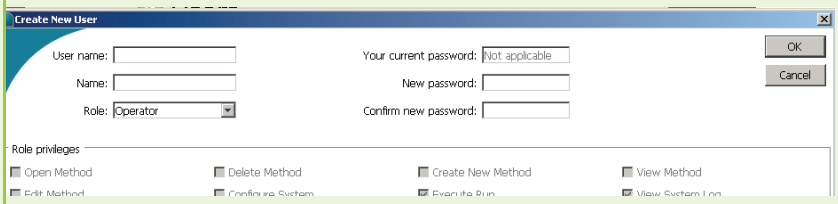


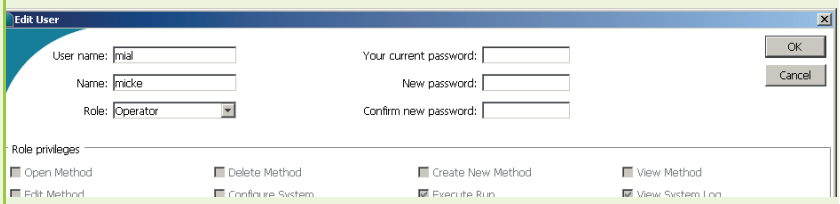
It is possible to perform six different administration tasks: **Create User, Edit User, Disable User, Export User List** and **Audit trail**.

NOTE: Select a user in the list to activate inaccessible task buttons.

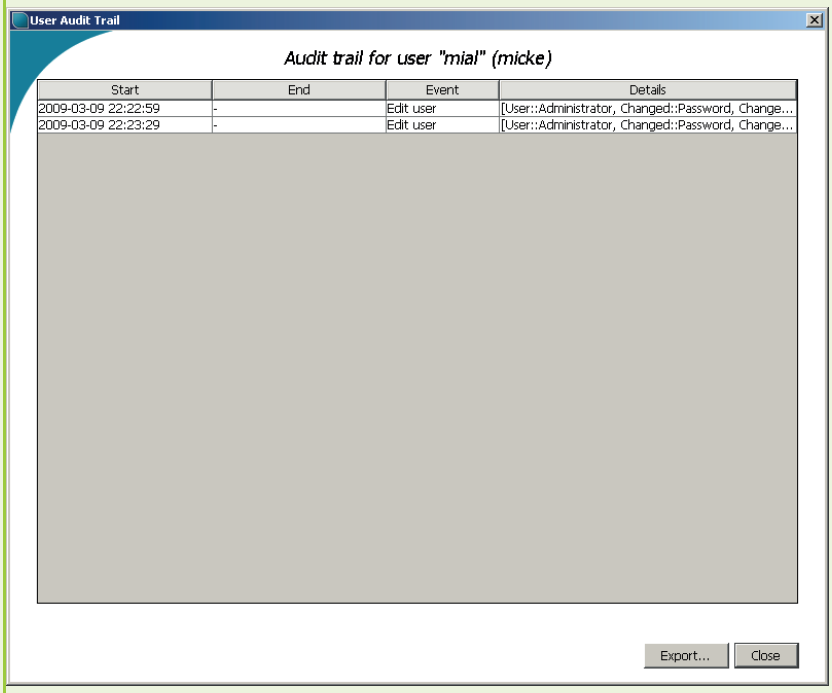
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Button	Action

Create User	**Create User** is used to create a new user. This action requires System Administrator privileges.
	• Click **Create User**.
	 
	• In the **Create New User** dialog:
	  • Enter **User Name**: Short name of user.
	  • Enter **Name**: Complete name of user.
	  • Select **Role** (user level): Select one user privilege category of **System Administrator, Method Developer, Project Manager** and **Operator.** Role privileges (user privileges) are displayed in the Role privileges section. Refer to Chapter F2.2.6.1 for more details.
	  • **New Password**: Enter the new user's password (Eight characters of which at least two must be numbers and at least two must be letters). This password is temporary, user is required to change password at the user´s next login.
	  • **Confirm New Password**: Enter the new user's password again.
	• Click **OK** in the **Create New User** dialog.
	The new user is now present in the user list in the **Users** screen. **User name, Name** and **Role** are displayed.

Edit User	**Edit User** is used for change users' privileges. This action requires **System Administrator** user level. • Click **Edit User**.  • In the **Edit User** dialog edit settings, edit **User Name**, **Name, Role** (user level), **New Password** and **Confirm New Password** as described in the previous Create User section. • Enter your own password in the **Your current password** field, e.g. if you are logged in as administrator, use the administrator password as **Your current password**. • Click **OK** in the **Edit User** dialog. The edited user is now updated. **User name, Name** and **Role** are displayed.
Export User List	Click **Export User List** button. The **Export User List** dialog will open. Browse for desired folder location and click **Export**. A User List in xml-format is created.

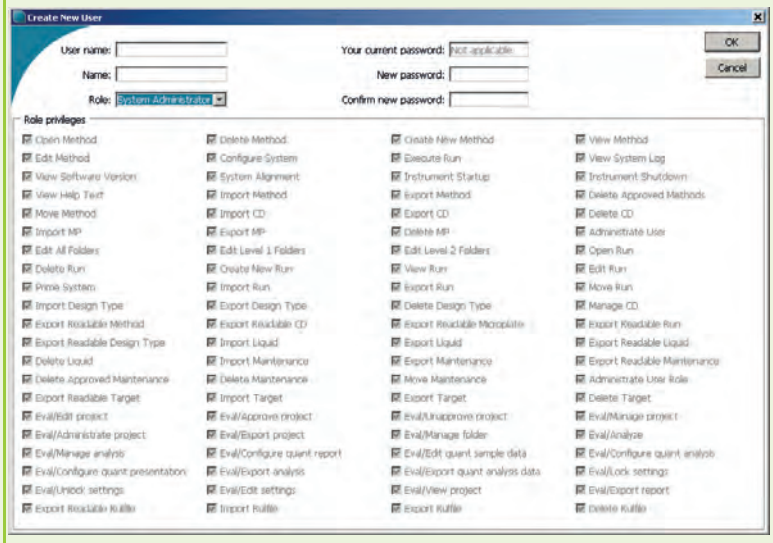
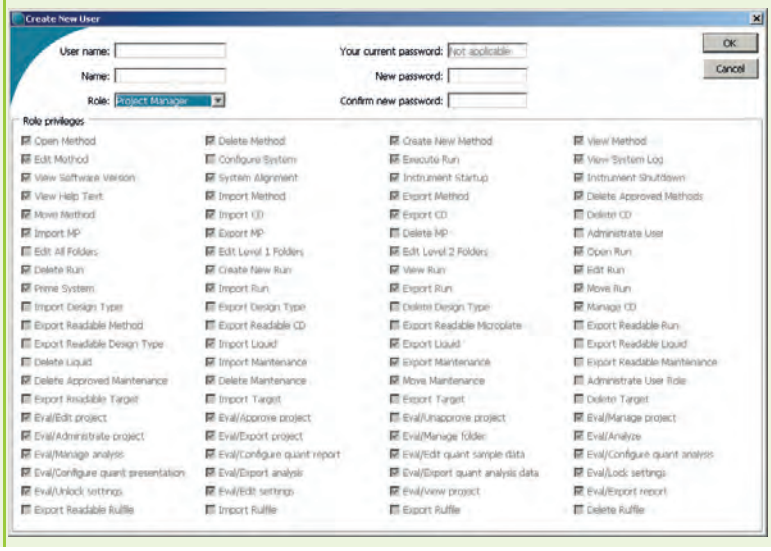
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Button	Action
Audit Trail	Select a desired user and click **Audit Trail** button.  A record of all user editing that has occurred for the selected user is displayed. • Click **Export** to export a text file of the user editing record. • Click **Close** to close the Audit Trail dialog.
Disable	**Disable** is used to disable an existing user. Disabling a user will lock the account and prevent the user from logging into Gyrolab software. • Select a user in the **Users** screen lists. • Click **Disable**. • Click **OK** in the **Disable User** dialog to confirm. The selected user is kept in the **Users** screen list, but when the disabled user is selected, information about is displayed. To re-enable a disabled user, assign the user a new password, se **Create User** part in this table

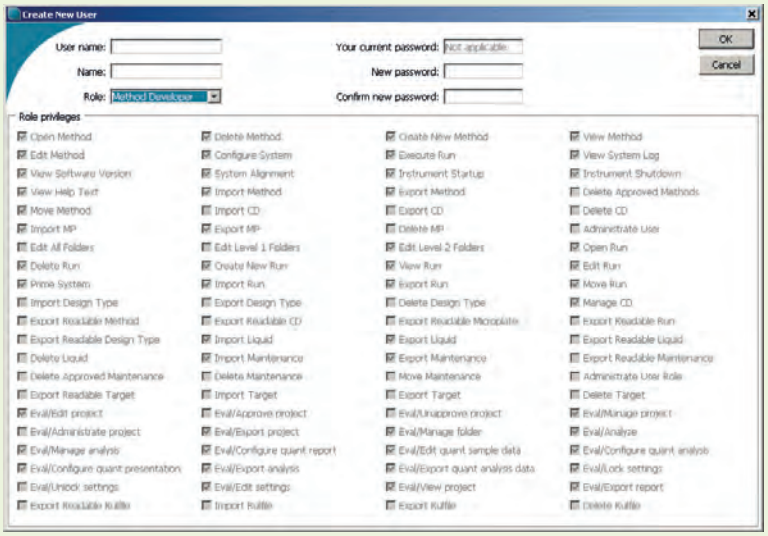
Click on **Close** in the top right hand corner of the **Users** screen to exit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.6.1 User level descriptions

User level	Description
System Administrator	**System Administrators** have unlimited user privileges. They can perform all actions of all other user levels as well as some actions unique to System Administrators such as creating and editing other users. Complete user level privileges are indicated by ticked boxes below.  **User Name** and **Password** for Gyrolab Software for one System Administrator user is provided by Gyros during customer training. It is the customers responsibility to change **User Name** and **Password** for this user to prevent unauthorized use of Gyrolab software.
Project Manager	A **Project Manager** can perform administrative tasks such as create folders, import and export objects in Administration Tool and approve projects in Gyrolab Evaluator. In addition, a **Project Manager** can perform all actions of **Operators** and **Method Developers**. Complete user level privileges are indicated by ticked boxes below. 

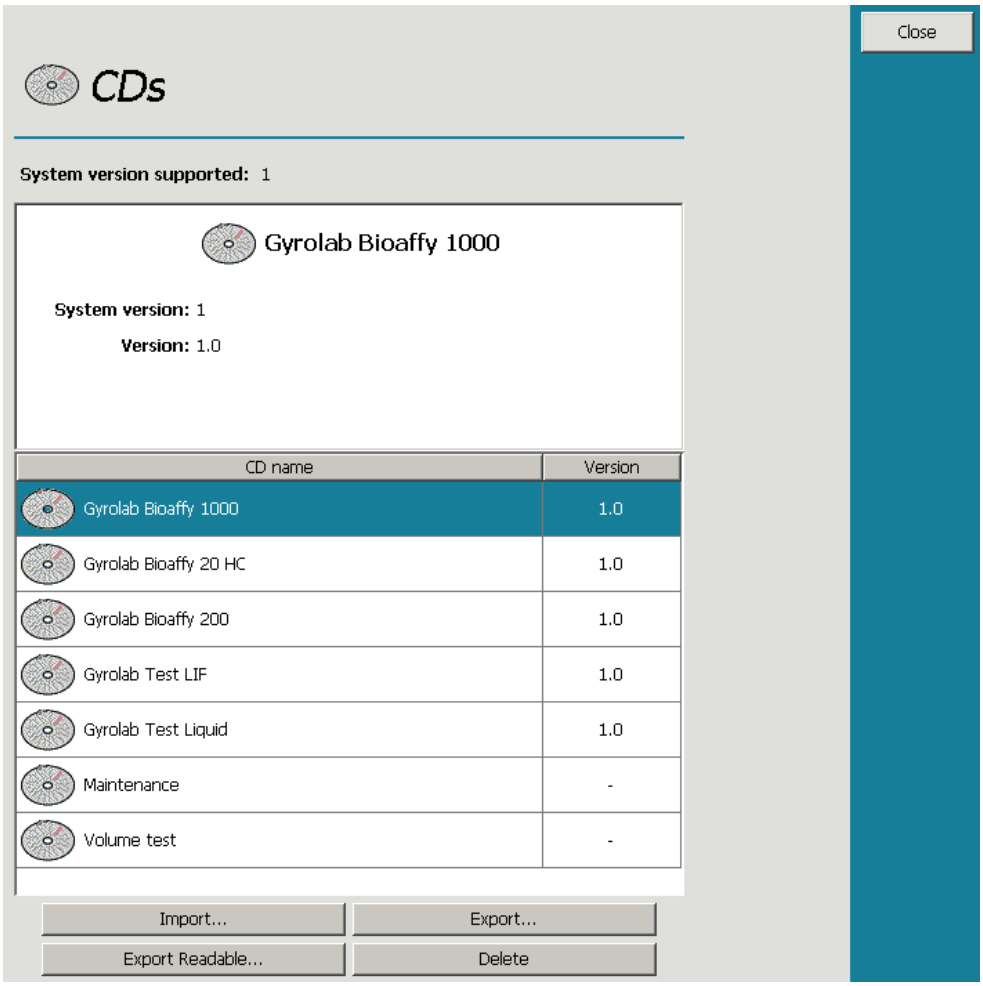
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

User level	Description
Method Developer	A **Method Developer** can develop methods and configure or align the system. In addition, a **Method Developer** can perform all actions of **Operators**. Complete user level privileges are indicated by ticked boxes below. 
Operator	An **Operator** can perform runs, but cannot edit existing runs or configure the system. Complete user level privileges are indicated by ticked boxes below.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.7 CDs

Click on **CDs** on the main menu to access the **CDs** screen. The **CDs** screen lists available CD microlaboratories.



It is possible to perform four different administration tasks: **Import, Export, Export Readable** and **Delete**.

NOTE: Select a CD in the list to activate inaccessible task buttons.

Button	Action
Import	**Import** is used to import a CD into Administration Tool to make it available for use in Gyrolab Control. • Click **Import** to open **Import CD** dialog. • Browse and select desired CD. CDs must be in `.zml` format. • Click **Import**. • Click **OK** in the **Import CD** dialog to confirm import. The selected CD is now present in the list in the **CDs** screen.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

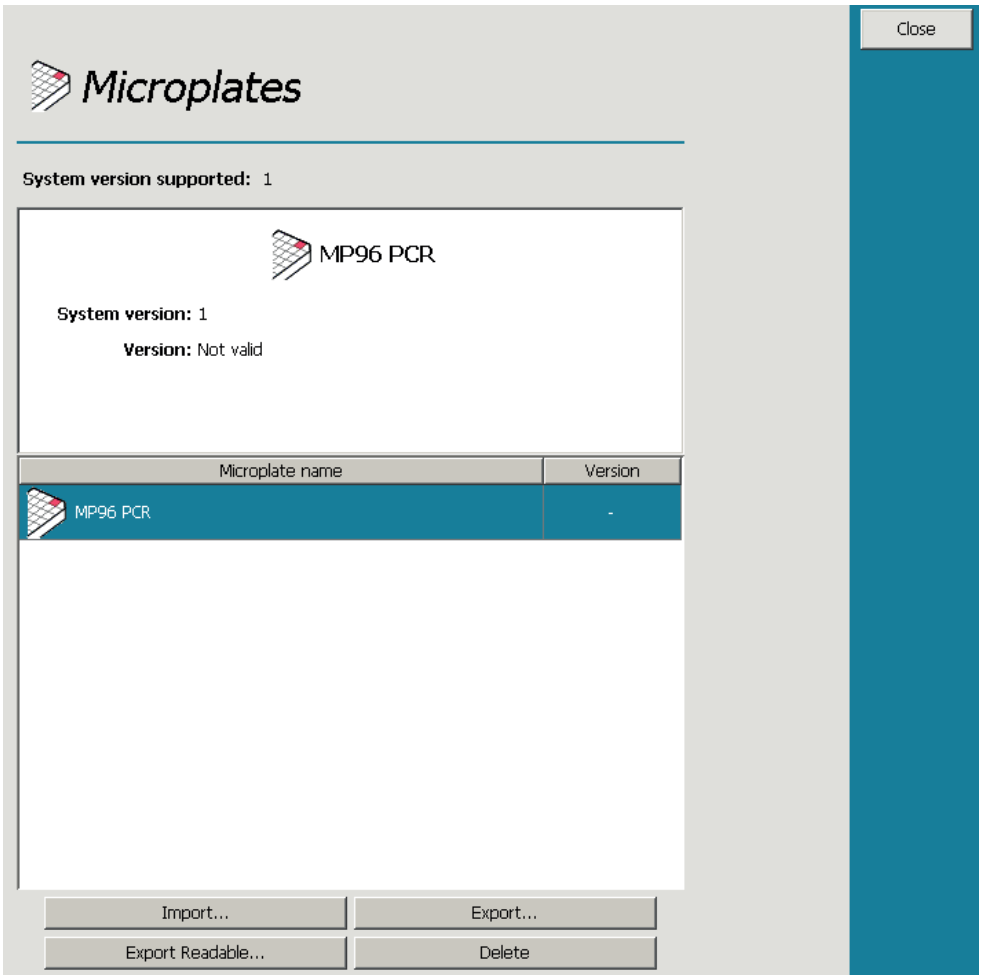
Button	Action
Export	**Export** is used to export CDs from Administration Tool. Exported CD can be imported into another Gyrolab instrument. • Select CD to export in the **CD** screen list. • Click **Export** to open **Export CD** window. • Browse and select desired export folder. • Click **Export**. • Click **OK** in the **Export CDs** dialog to confirm export. The selected CD is now present in the selected export folder.
Export readable	**Export Readable** is used to export a readable copy of a CD. This copy cannot be used in Gyrolab Control but it can be useful for example when contacting Gyros for support. • Select CD in the **CD** screen list. • Click **Export readable** to open **Export CD in readable format** dialog. • Browse and select desired export folder. • Click **Export readable**. • Click **OK** in the **Export Readable CD** dialog to confirm export readable. The selected CD is now present in a readable format in the selected export folder.
Delete	**Delete** is used to delete CD files. • Select item to be deleted from **CD** screen list. • Click **Delete**. • Click **OK** in the **Delete CD** dialog to confirm deletion. The selected CD is now deleted from the **CDs** screen list.

Click on **Close** in the top right hand corner of the **CDs** screen to exit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.8 Microplates

Click on **Microplates** on the main menu to access the **Microplates** screen. The **Microplates** screen lists available Microplates.



It is possible to perform four different administration actions: **Import, Export, Export Readable** and **Delete**.

NOTE: Select a microplate in the list to activate inaccessible task buttons.

Button	Action
Import	**Import** is used to import a Microplate file to Administration Tool to make it available for use in Gyrolab Control. • Click **Import** to open **Import Microplate** dialog. • Browse and select desired Microplate file. Microplate files must be in `.zml` format. • Click **Import**. • Click **OK** in the **Import Microplate** dialog to confirm import. The selected Microplate file is now present in the list in the **Microplates** screen.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

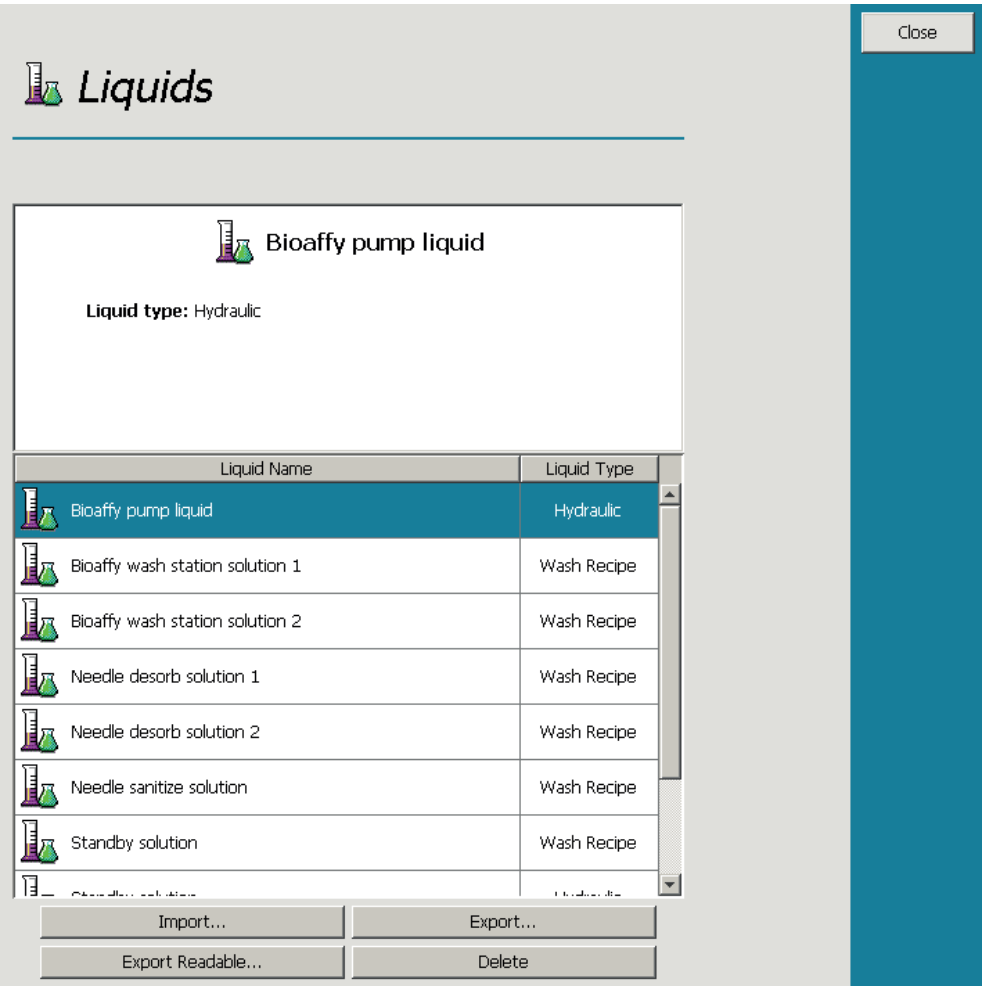
Button	Action
Export	Export is used to export Microplate files from Administration Tool. Exported microplate can be imported into another Gyrolab instrument. • Select Microplate file to export in the Microplate screen list. • Click Export to open Export Microplate window. • Browse and select desired export folder. • Click Export. • Click OK in the Export Microplates dialog to confirm export. The selected Microplate file is now present in the selected export folder.
Export readable	Export Readable is used to export a readable copy of a microplate. This copy cannot be used in Gyrolab Control but it can be useful for example when contacting Gyros for support. • Select Microplate in the Microplate screen list. • Click Export readable to open Export Microplate in readable format dialog. • Browse and select desired export folder. • Click Export readable. • Click OK in the Export Readable Microplate dialog to confirm export readable. The selected Microplate file is now present in a readable format in the selected export folder.
Delete	Delete is used to delete microplate files. • Select Microplate file to be deleted from Microplate screen list. • Click Delete. • Click OK in the Delete Microplate dialog to confirm deletion. The selected Microplate file is now deleted from the Microplates screen list.

Click on Close in the top right hand corner of the Microplates screen to exit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.9 Liquids

Click on **Liquids** on the main menu to access the **Liquids** screen. The **Liquids** screen lists available Liquids.



It is possible to perform four different administration actions: **Import, Export, Export Readable** and **Delete**.

NOTE: Select a liquid in the list to activate inaccessible task buttons.

Button	Action
Import	**Import** is used to import a Liquid to Administration Tool to make it available for use in Gyrolab Control. • Click **Import** to open **Import Liquid** dialog. • Browse and select desired Liquid. Liquids must be in `.zml` format. • Click **Import**. • Click **OK** in the **Import Liquid** dialog to confirm import. The selected Liquid is now present in the list in the **Liquids** screen.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

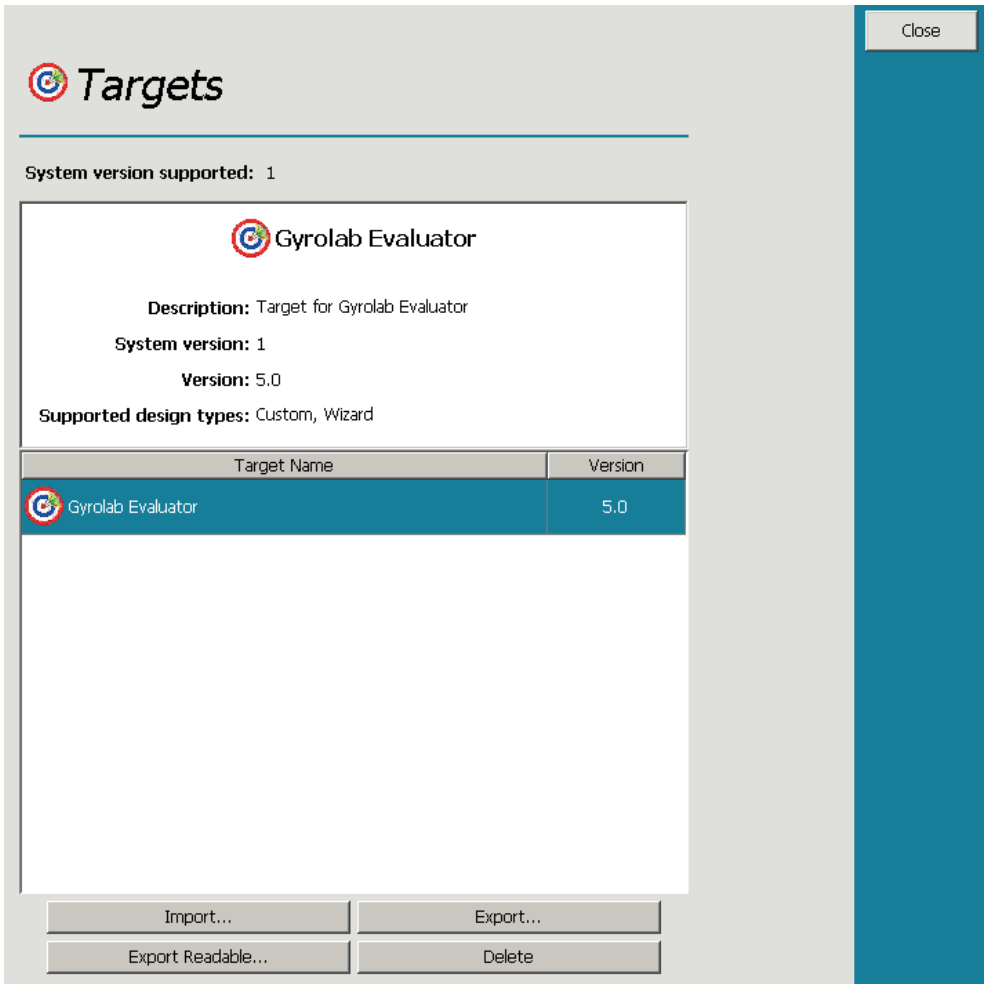
Button	Action
Export	**Export** is used to export Liquids from Administration Tool. Exported liquid can be imported into another Gyrolab instrument. • Select **Liquid** to export in the **Liquid** screen list. • Click **Export** to open **Export Liquids** window. • Browse and select desired export folder. • Click **Export**. • Click **OK** in the **Export Liquids** dialog to confirm export. The selected Liquid is now present in the selected export folder.
Export readable	**Export Readable** is used to export a readable copy of a liquid. This copy cannot be used in Gyrolab Control but it can be useful for example when contacting Gyros for support. • Select Liquid in the **Liquid** screen list. • Click **Export readable** to open **Export Liquid in readable format** dialog. • Browse and select desired export folder. • Click **Export readable**. • Click **OK** in the **Export Readable Liquid** dialog to confirm export readable. The selected Liquid is now present in a readable format in the selected export folder.
Delete	**Delete** is used to delete Liquid files. • Select item to be deleted from **Liquid** screen list. • Click **Delete**. • Click **OK** in the **Delete Liquid** dialog to confirm deletion. The selected Liquid is now deleted from the **Liquids** screen list.

Click on **Close** in the top right hand corner of the **Liquids** screen to exit.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F2.2.10 Targets

Click on **Targets** on the main menu to access the **Targets** screen. The **Targets** screen lists available Targets.



It is possible to perform four different administration actions: **Import, Export, Export Readable** and **Delete**.

NOTE: Select a target in the list to activate inaccessible task buttons.

Button	Action
Import	**Import** is used to import a Target to Administration Tool to make it available for use in Gyrolab Control. • Click **Import** to open **Import Targets** dialog. • Browse and select desired Target. Targets must be in `.zml` format. • Click **Import**. • Click **OK** in the **Import Target** dialog to confirm import. The selected Target is now present in the list in the **Targets** screen.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

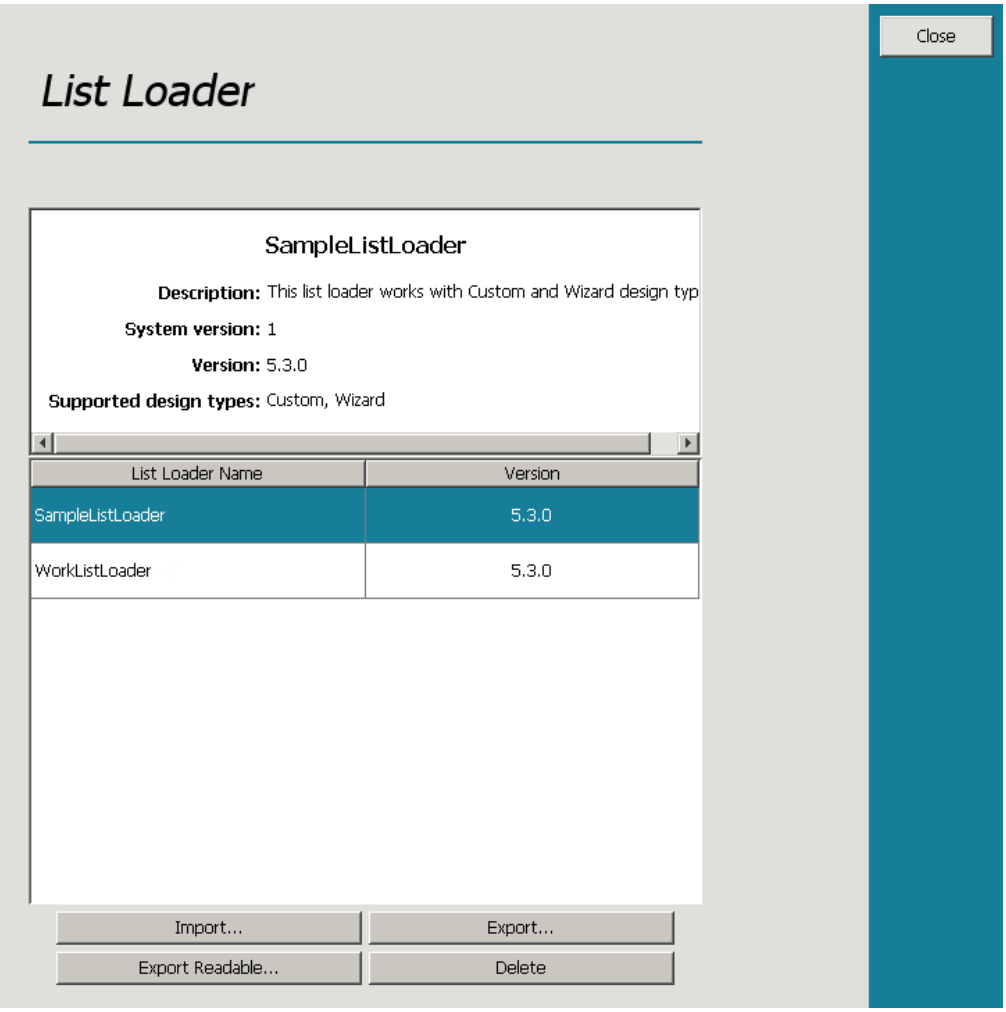
Button	Action
Export	Export is used to export Targets from Administration Tool. Exported target can be imported into another Gyrolab system. • Select Target to export in the Target screen list. • Click Export to open Export Targets window. • Browse and select desired export folder. • Click Export. • Click OK in the Export Targets dialog to confirm export. The selected Target is now present in the selected export folder.
Export readable	Export Readable is used to export a readable copy of a target. This copy cannot be used in Gyrolab Control but it can be useful for example when contacting Gyros for support. • Select Target in the Target screen list. • Click Export readable to open Export Target in readable format dialog. • Browse and select desired export folder. • Click Export readable. • Click OK in the Export Readable Target dialog to confirm export readable. The selected Target is now present in a readable format in the selected export folder.
Delete	Delete is used to delete Target files. • Select item to be deleted from Target screen list. • Click Delete. • Click OK in the Delete Target dialog to confirm deletion. The selected Target is now deleted from the Targets screen list.

Click on Close in the top right hand corner of the Targets screen to exit.

F2.2.11 List Loaders

Click on List Loaders on the main menu to access the SampleListLoader screen. The SampleListLoader screen lists available List loader files.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A



It is possible to perform four different administration actions: **Import**, **Export**, **Export Readable** and **Delete**.

NOTE: Select a List Loader in the list to activate inaccessible task buttons.

Button	Action
Import	**Import** is used to import a List Loader to the Administration Tool to make it available for use in Gyrolab Control. • Click **Import** to open **Import Rulfile** dialog. • Browse and select desired List Loader file. List loaders must be in `.zml` format. • Click **Import**. • Click **OK** in the **Import Rulfile** dialog to confirm import. The selected List Loader is now present in the list in the **SampleListLoader** screen.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Button	Action
Export	**Export** is used to export List Loaders from the Administration Tool. Exported List Loader can be imported into another Gyrolab system. • Select List Loader to export in the SampleListLoader screen list. • Click **Export** to open **Export List Loader** window. • Browse and select desired export folder. • Click **Export**. • Click **OK** in the **Export List Loader** dialog to confirm export. The selected List Loader is now present in the selected export folder.
Export readable	**Export Readable** is used to export a readable copy of a List Loader. This copy cannot be used in Gyrolab Control but it can be useful for example when contacting Gyros for support. • Select List Loader in the SampleListLoader screen list. • Click **Export readable** to open **Export Target in readable format** dialog. • Browse and select desired export folder. • Click **Export readable**. • Click **OK** in the **Export List Loader in Readable Format** dialog to confirm export readable. The selected List Loader is now present in a readable format in the selected export folder.
Delete	**Delete** is used to delete List Loader files. • Select item to be deleted from SampleListLoader screen list. • Click **Delete**. • Click **OK** in the **Delete List Loader** dialog to confirm deletion. The selected Target is now deleted from the SampleListLoader screen list.

Click on **Close** in the top right hand corner of the SampleListLoader screen to exit.

F2.2.12 About function

Click **About** to get information about the software versions and licences for Administration Tool.

F2.2.13 Logout

Click **Logout** to log out and shut down Administration Tool.

F2.2.14 Help

To access the help section (a pdf version of Gyrolab User Guide), click **Help** on the main menu and browse for needed Gyrolab User Guide chapter.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F3 Gyrolab Result Database Explorer

F3.1 Introduction

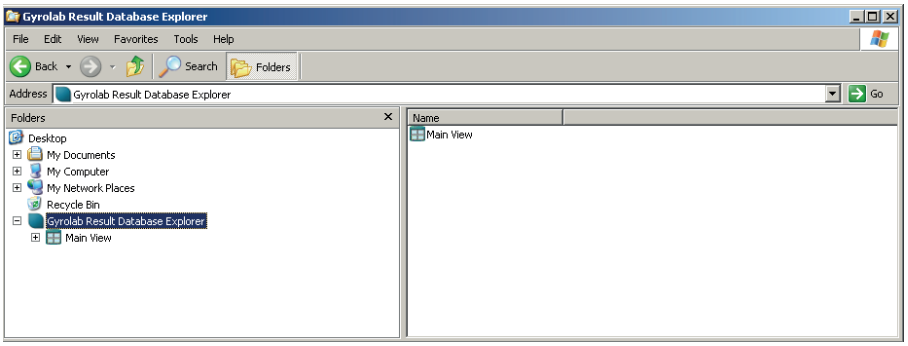
Files that are generated by Gyrolab Control during a Run are saved in **Gyrolab Result Database**. The files are kept in a read only state and can not be changed, moved or deleted.

Use Gyrolab Result Database Explorer to:

- view database files, Chapter F3.2.
- customize database view, Chapter F3.3.
- export copies of Result files and Report files, Chapter F3.4.
- generate status reports, Chapter F3.5.

F3.2 View database files

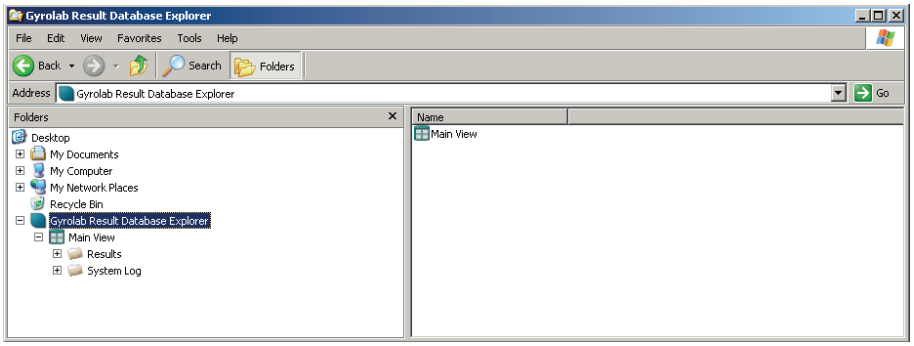
Step	Action
1.	To open Gyrolab Result Database Explorer: • Open Windows Explorer. • Click on **Gyrolab Result Database Explorer**.
2.	**Gyrolab Result Database Explorer** window opens. Click **Folders**.



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

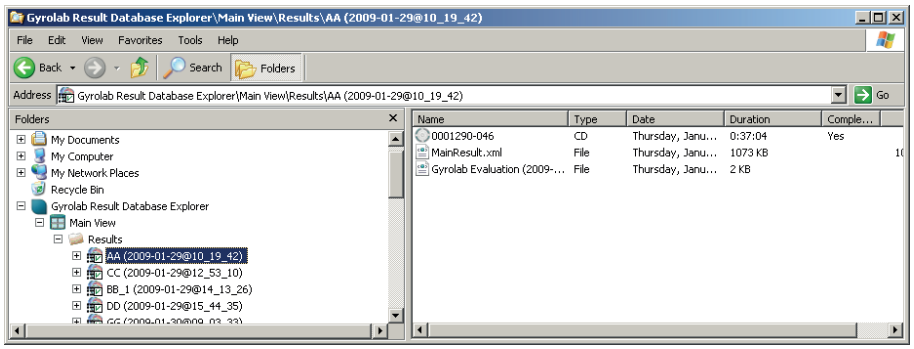
Step	Action

3. Click **Main View**. The folders **Results** and **System log** appear.



NOTE: ***It is possible to create customized database views in Gyrolab Result Database Explorer to facilitate finding specific database files, refer to Chapter F3.3.***

4. Click **Results** for a list of Runs stored in the database. Click on the icon for the Run of interest.



Available files:

- **CD images** (file(s) are named according CD identity number). Contains fluorescence images from the CD in a ZIP file.
- **MainResult.xml** is the archive file. It contains all results from a Run, processed for further use by Gyrolab Evaluator or for export to a LIMS.
- **Gyrolab Evaluator** is the result file.

NOTE: ***Files in Gyrolab Result Database have read only status. Make a copy if editing is desired: open the file, click*** **Save as** ***and save a working copy of the file at a desired folder.***

5. **System Log** holds the Audit Trail for a specific system. All instrument events are logged. Files in the System Log may be useful during troubleshooting.

6. Click **File:Close** to close Gyrolab Result Database Explorer.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

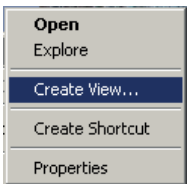
F3.3 Customize database view

It is possible to create a customized database view by filtering for result files with specific properties. Customized views minimizes time-consuming browsing for result files when Gyrolab Result Database holds a large quantity of results.

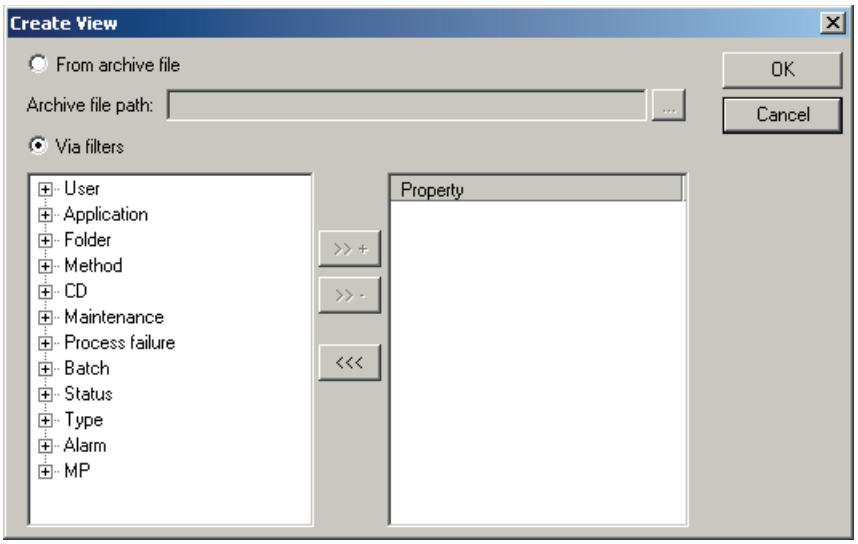
Step Action

1. To open Gyrolab Result Database Explorer:.

- Open Windows Explorer.
- Right-click on Gyrolab Result Database Explorer and select **Create view.**



2. The **Create View** dialog opens.



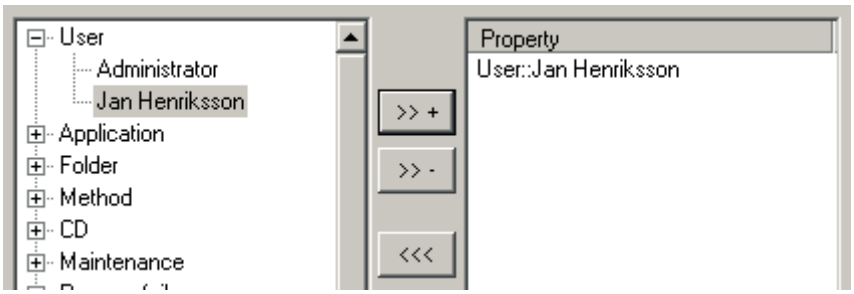
A number of filter categories are shown (User, Design type, etc.). For each category one or more properties are listed. Click the expander button for a category to display available properties.

3. To **Include** a property in a customized database view:

- Click the ⊞ icon for the category and select item.

- Click **Include** button.

.
- Repeat this procedure to include additional properties. All selected items are displayed in the Property list according to **Category name:Property name.**



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

4. To **Exclude** an item in a category from the customized database view:

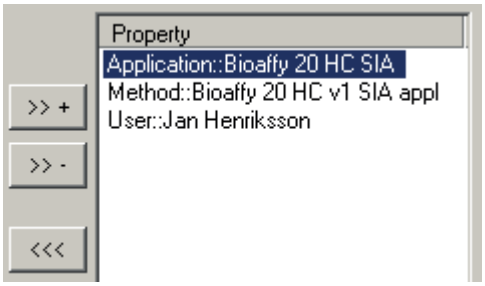
- Click the ⊞ icon for the category and select item.

- Click **Exclude** button.

- Repeat this procedure to exclude additional properties. All excluded items are displayed in the **Property** list according to **NOT Category name:Property name**

5. To **Remove** a property from the **Property** list:

- Select the property to remove.

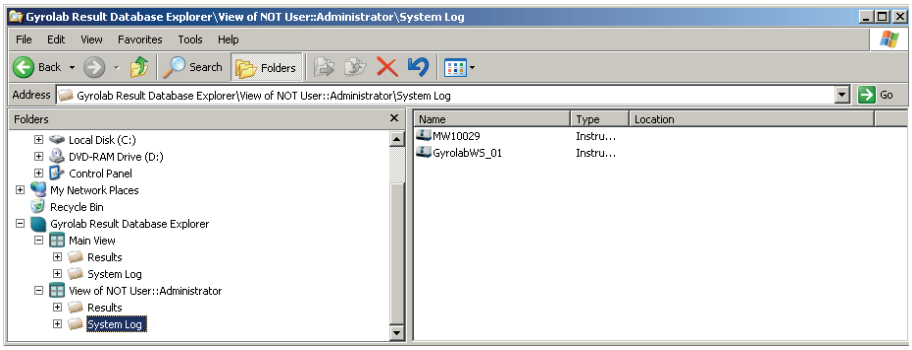


- Click **Remove** button.

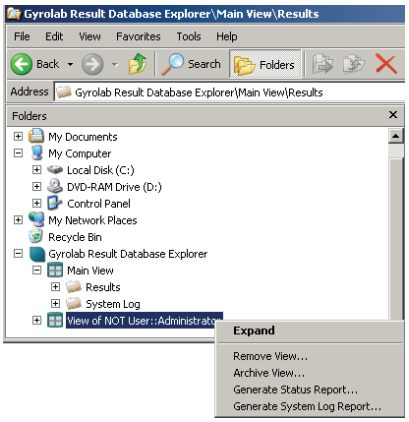
. The selected item is now removed from the **Property** list.

6. Click **OK** when all wanted properties are **Included** and/or **Excluded**.

7. The customized database view, including corresponding **Results** and **System Log** folders, is now available below the main view in the tree structure in **Gyrolab Result Database Explorer** window.

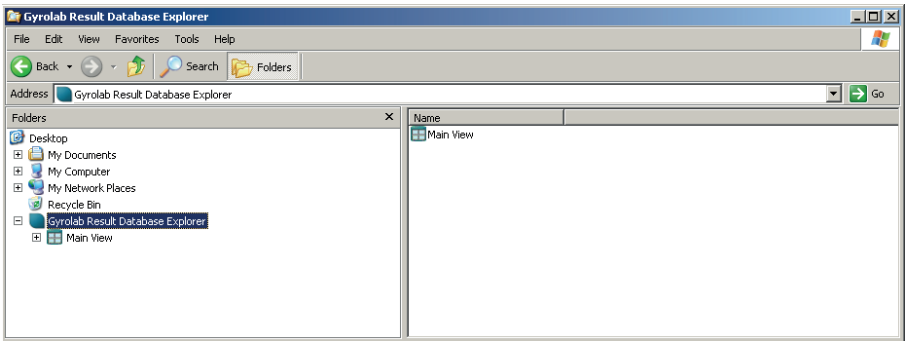


© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
8.	To remove a customized database view: Right-click on the customized database view to be removed. Select **Remove View**  The selected customized database view is now removed from Gyrolab Result Database Explorer.

F3.4 Generate Result Reports

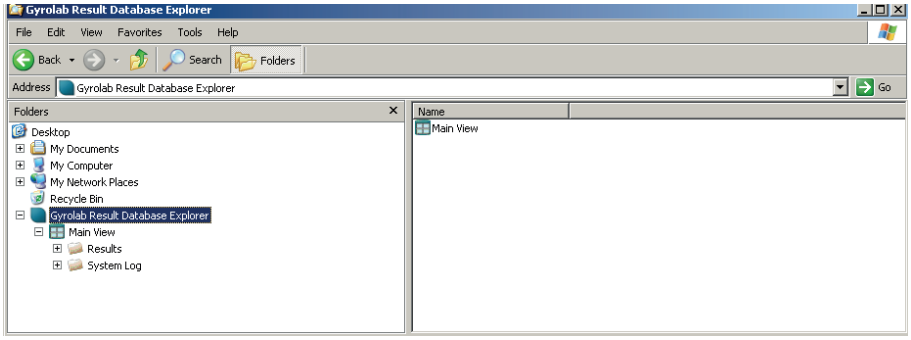
Result reports contain result and system log files for a specific run and are exported from Gyrolab Result Database Explorer. Output format is `.gyr` which is a compressed format suitable to e-mail to Gyros' support function.

Step	Action
1.	To open Gyrolab Result Database Explorer: • Open Windows Explorer. • Click on **Gyrolab Result Database Explorer**.
2.	**Gyrolab Result Database Explorer** window opens. Click **Folders**. 

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

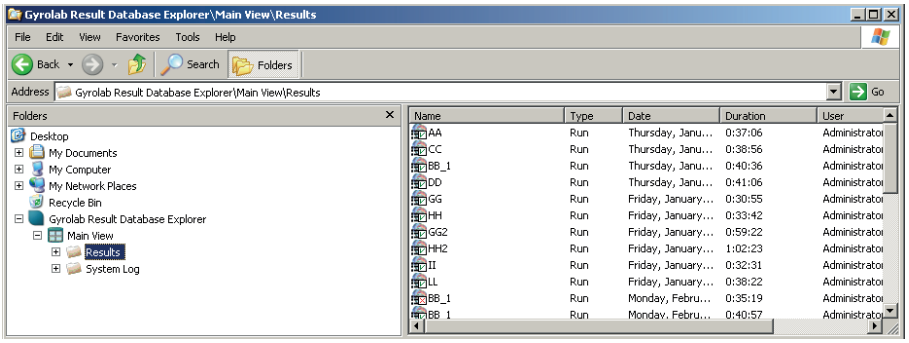
Step	Action

3. Click **Main View**. The folders **Results** and **System log** appear.



NOTE: ***It is possible to create customized database views in Gyrolab Result Database Explorer to facilitate finding specific database files, refer to Chapter F3.3.***

4. Click **Results** for a list of Runs stored in the database. Click on the icon for the Run of interest.


Gyrolab Result Database Explorer\Main View\Results
File Edit View Favorites Tools Help
Back Search Folders
Address Gyrolab Result Database Explorer\Main View\Results
Go
Folders
Desktop
My Documents
My Computer
My Network Places
Recycle Bin
Gyrolab Result Database Explorer
Main View
Results
System Log
Name Type Date Duration User
AA Run Thursday, Janu... 0:37:06 Administrator
CC Run Thursday, Janu... 0:38:56 Administrator
BB_1 Run Thursday, Janu... 0:40:36 Administrator
DD Run Thursday, Janu... 0:41:06 Administrator
GG Run Friday, January... 0:30:55 Administrator
HH Run Friday, January... 0:33:42 Administrator
GG2 Run Friday, January... 0:59:22 Administrator
HH2 Run Friday, January... 1:02:23 Administrator
II Run Friday, January... 0:32:31 Administrator
LL Run Friday, January... 0:38:22 Administrator
BB_1 Run Monday, Febru... 0:35:19 Administrator
BB_1 Run Monday, Febru... 0:40:57 Administrator

5. Highlight the desired Result file, right-click and select **Generate result report...**

6. In the **Save As** dialog, name the result report file and browse for desired location. The location must be at the local disc, usually the C disc.

Click **Save**.

7. The exported result report is now found at its specified location. The file contains run results and system log for the specific run and is compressed to .gyr format.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

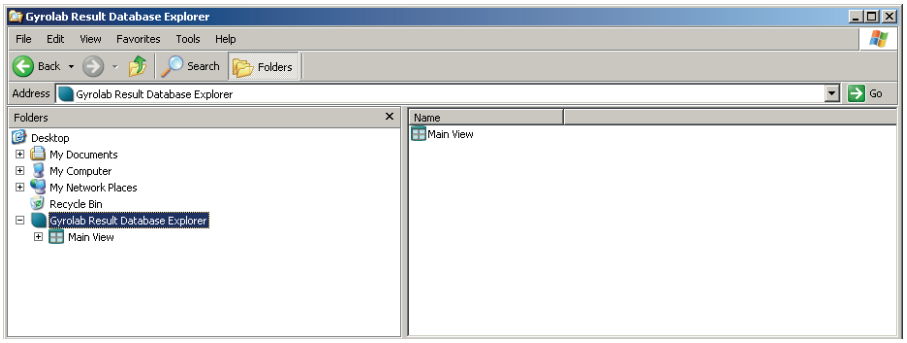
F3.5 Generate Gyrolab Control Audit Trail report

An Audit Trail report includes all system log files within specified dates set by the user. No result files are included in Audit Trail reports. Two alternatives are available: compressed .gyr format and readable XML format.

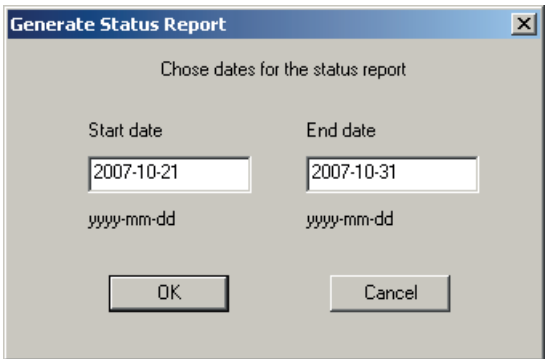
F3.5.1 Compressed Audit Trail report – Status Report

A compressed Audit Trail report is called a **Status Report**. Output format is .gyr which is a compressed format suitable to e-mail to Gyros' support function. Since this report does not contain any run data it can be used for support matters where data can not be shared for some reason.

Step	Action
1.	To open Gyrolab Result Database Explorer: • Open Windows Explorer. • Click on **Gyrolab Result Database Explorer**.
2.	**Gyrolab Result Database Explorer** window opens. Click **Folders**.



3.	Right-click **Main View** and select **Generate Status Report**.
4.	Set **Start date** and **End date** for the status report. Default setting is 10 days from current date.



Click **OK**.

5.	In the **Save As** dialog, name the status report file and browse for desired location. The location must be at the local disc, usually the C disc. Click **Save**.
6.	The exported status report is now found at its specified location. The file contains the instrument audit trail (system log) and is compressed to .gyr format.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

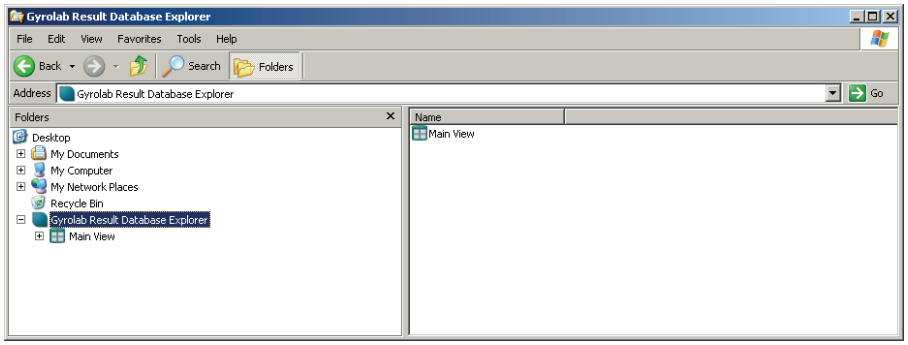
F3.5.2 Readable Audit Trail Report – System Log Report

A readable Audit Trail report is called a **System log Report**. Output format is .XML which is a readable format suitable to archive or study at user site. Since this report does not contain any run data it can be used when data can not be shared for some reason.

Step	Action

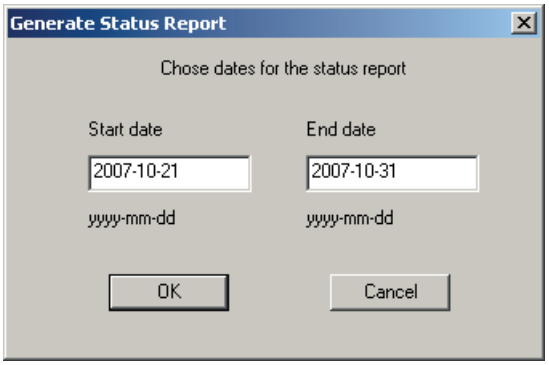
1. To open Gyrolab Result Database Explorer, open Windows Explorer and click on **Gyrolab Result Database Explorer**.

2. **Gyrolab Result Database Explorer** window opens. Click **Folders**.



3. Right-click **Main View** and select **Generate Status Report**.

4. Set **Start date** and **End date** for the status report. Default setting is 10 days from current date.



Click **OK**.

5. In the **Save As** dialog, name the status report file and browse for desired location. The location must be at the local disc, usually the C disc.

   Click **Save**.

6. The exported status report is now found at its specified location. The file contains the instrument audit trail (system log) and is compressed to .gyr format.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F4 Gyrolab Database Backup Manager

Gyrolab Database Backup Manager is used to back up the data stored in Gyrolab Result Database. Backup of the database is not performed automatically by Gyrolab software. Gyrolab users must create their own routines and set time intervals for data backup. Backup can be performed manually at certain time points or set up as a scheduled, repetitive task.

TIP: ***It is strongly recommended to store the backup data at a different location than the Gyrolab computer.***

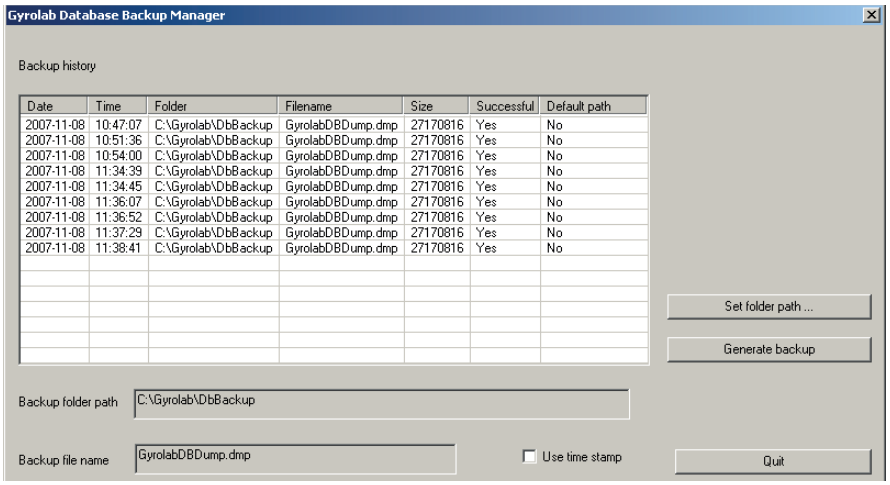
F4.1 Perform Gyrolab database back up

Step	Action

1. To open Gyrolab Database Backup Manager:

Select **Start:All Programs:Gyros:Gyrolab Control:Gyrolab DB Backup Manager**.

Gyrolab Database Backup Manager dialog opens. The list displays backup history.


Gyrolab Database Backup Manager
Backup history
Date Time Folder Filename Size Successful Default path
2007-11-08 10:47:07 C:\Gyrolab\DbBackup GyrolabDBDump.dmp 27170816 Yes No
2007-11-08 10:51:36 C:\Gyrolab\DbBackup GyrolabDBDump.dmp 27170816 Yes No
2007-11-08 10:54:00 C:\Gyrolab\DbBackup GyrolabDBDump.dmp 27170816 Yes No
2007-11-08 11:34:39 C:\Gyrolab\DbBackup GyrolabDBDump.dmp 27170816 Yes No
2007-11-08 11:34:45 C:\Gyrolab\DbBackup GyrolabDBDump.dmp 27170816 Yes No
2007-11-08 11:36:07 C:\Gyrolab\DbBackup GyrolabDBDump.dmp 27170816 Yes No
2007-11-08 11:36:52 C:\Gyrolab\DbBackup GyrolabDBDump.dmp 27170816 Yes No
2007-11-08 11:37:29 C:\Gyrolab\DbBackup GyrolabDBDump.dmp 27170816 Yes No
2007-11-08 11:38:41 C:\Gyrolab\DbBackup GyrolabDBDump.dmp 27170816 Yes No
Set folder path ...
Generate backup
Backup folder path
C:\Gyrolab\DbBackup
Backup file name
GyrolabDBDump.dmp
Use time stamp
Quit

2. To set location for database backup:

- Click **Set folder path.**

NOTE: ***Note that it is recommended to save the backup separate from the C: drive if the C: drive would crash. It is also recommended to put the database backup at a location where regular backup is taken, e.g. on a network server.***

- Browse for the desired folder and click **OK**.

The selected folder is shown in the **Backup folder path** field.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
3.	Check or un-check the **Use time stamp** box: • If **Use time stamp** is checked, the time and date for the database backup will be included in the database backup file name. Each database backup file will have a unique name and the risk of replacing old back up files is minimized. • If **Use time stamp** is not checked, the database backup file will be saved under the standard name in the selected folder and any previous database backup files without time stamps in the same folder will be replaced. The name for the database backup file is shown in the **Backup file name** field.
4.	Click **Generate backup**. The back up file is not available in the set folder destination.
5.	To close Gyrolab Database Backup Manager: Click **Quit**.

F4.2 Schedule Gyrolab data base backup

Database backup can be scheduled as a one time event or as a recurring action using the Windows Task Scheduler.

Refer to Windows Help for instructions on how to perform a scheduled task.

Chose Gyrolab Database Backup Manager to run as a recurring task. The path to the software is `C:\Program Files\Gyros\Gyrolab\Bin\GyrolabDbBackupMan.exe`.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F5 Gyrolab Set System Time

F5.1 Gyrolab Set System Time introduction

Gyrolab Set System Time is a software tool that enables Gyrolab users to change system time in a controlled manner. All changes of system time will be recorded in the audit trail. Only System Administrators can change system time. The System Administrator must also have Windows system privileges for the computer.

F5.2 Perform logged system time change

Step	Action
1.	Close all open Gyrolab software applications open including the server.
2.	Select **Start:All Programs:Gyros:Gyrolab Control:Gyrolab Set System Time.**
3.	Enter user name and password in the **Login** dialog box and click **OK**.

The user name and password is the same for all Gyrolab software. For further information on user and password administration, refer to Chapter F2.2.6.

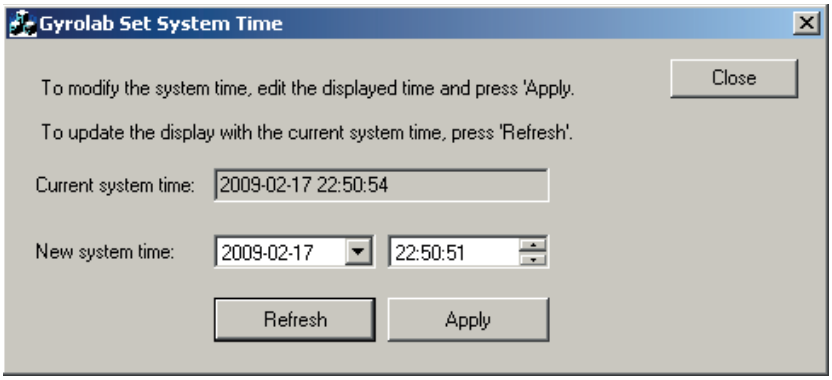
Password must be changed if requested by the software, for example when a new user logs in or if 90 days have passed since last password change. Password may also be changed when desired by the user. To change password:

- Mark the check-box **Change Password.**
- Enter current password in **Password** field, new password in **New Password** field and confirm new password in **Confirm Password** field.
- Click **OK**.

NOTE: User name and password are case sensitive.

NOTE: The software will request the user to log in anew when the system has been inactive for 31 minutes.

4. **Gyrolab Set System Time** dialog opens.



- Set **New system time**: (date and time).
- Click **Refresh** to update the fields in New System Time to the current system time.
- Click **Apply**.
- Click **Close**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

F5.3 Non-logged system time changes

System time can also be changed manually using the regular Windows® tools or by automatic updates. However, system time changes will only be added to the audit trail if the Change System Time tool is used.

Automatic updates of system time can occur when:

- The instrument computer is included in a Windows domain where system time is controlled by domain policies.
- The instrument computer is configured to automatically adjust the system time to correlate with an external time server.
- The instrument computer is set to automatically adjust to daylight saving time changes.

If it is vital to include all system time changes in the audit trail, make sure to exclude these time change sources by taking the following steps:

- Do not add the instrument computer to a windows domain, or make sure that there are no policies adjusting the system clock on the instrument computer.
- Disable synchronization with external time servers, and daylight saving adjustments, using the Windows Control Panel **Date and Time** tool.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

GYROLAB USER GUIDE

G Troubleshooting

Contents

G1 Instrument issues G-3

G1.1 Instrument initialization problems G-3

G1.2 Instrument computer contact G-7

G1.3 Gyrolab xPlore front panel LEDs G-7

G2 Software issues G-9

G2.1 Gyrolab Control G-9

G2.2 Gyrolab Result Database Backup Manager G-9

G2.3 Gyrolab Evaluator G-10

G3 Application issues G-11

G3.1 No response values are generated G-11

G3.2 Unexpected appearance of standard curve G-11

G3.2.1 Laboratory and instrument generated errors G-11

G3.2.2 Low response G-12

G3.2.3 Extensive variation G-12

G3.2.4 Detect result -Not OK in Gyrolab Evaluator result file G-13

G3.2.5 Elevated background G-14

G3.3 Problems with outliers G-15

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

G3.4 Poor recovery of proteins after using Nanosep G–15

G3.5 Poor precision and bad reproducibility between runs..... G–15

G3.6 Increased background in lower parts of the CD column..... G–15

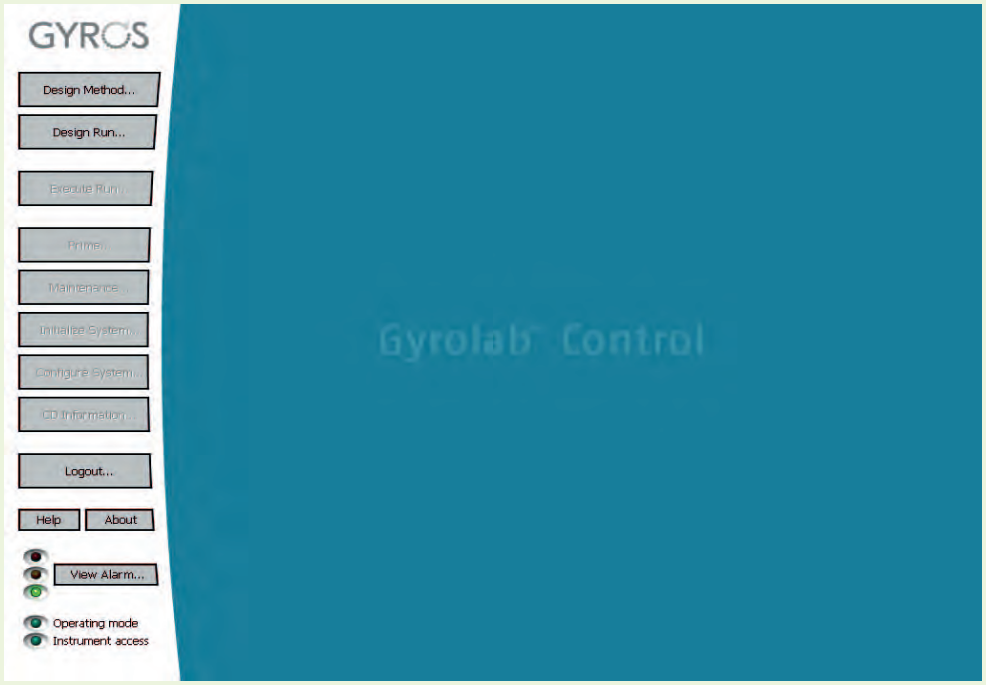
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

G1 Instrument issues

This section contains information on how to diagnose and possibly solve problems related to all Gyrolab instrument. Always start the troubleshooting by checking the connection between the computer and the instrument and restart the instrument and the computer. If you cannot identify the problem, or if the problem remains, please contact Gyros for support.

G1.1 Instrument initialization problems

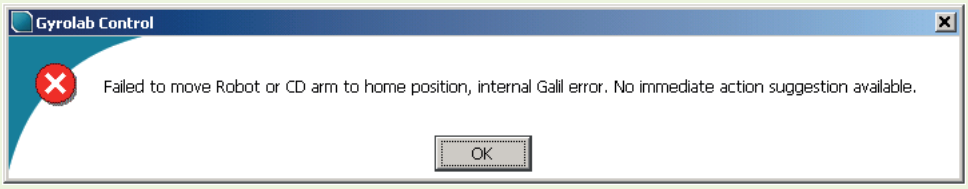
The instrument initialization problems described in this section applies for all Gyrolab Instruments.

Error message/Possible cause	Action
	
Example of error message: • No instrument access. • Initialize System button disabled (greyed out). Possible cause: • Gyrolab Control software turned on without restarting the instrument.	• Check the connection between the computer and the instrument. • Restart the instrument. • If still no instrument connection, restart the computer. • If you cannot identify the problem, or if the problem remains, please contact Gyros for support.

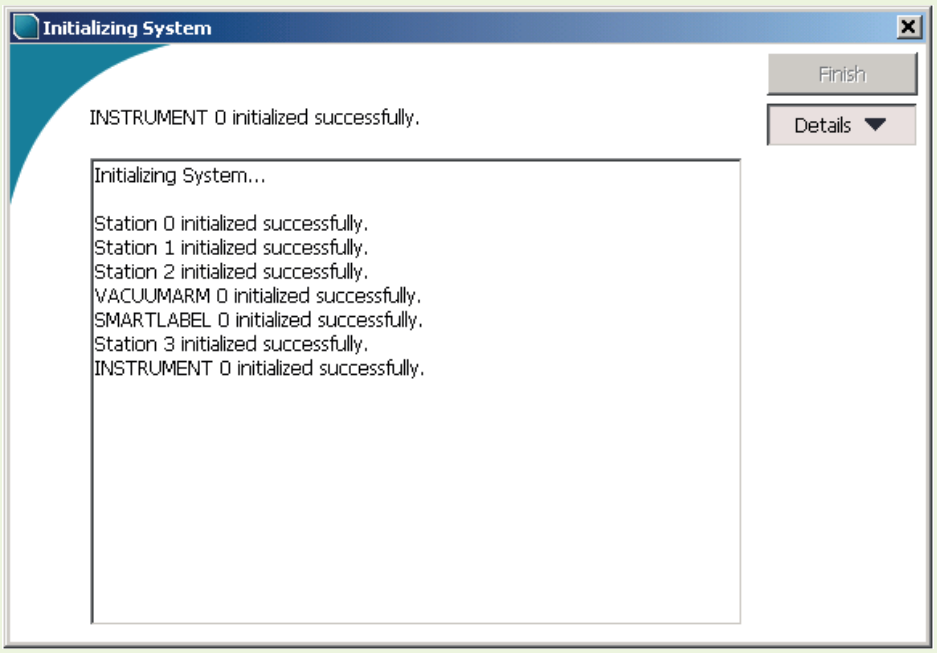
The instrument initialization problems described in this section applies for Gyrolab Instruments with serial numbers up to 158.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Error message/Possible cause	Action
Examples of error messages: • Robot, Carousel or CD-arm timed out. Software error. No immediate action suggestion available, example in figure below Possible cause: • Dislocated Controller cables	• Check Controller cable 1, refer to Chapter A2.3. • Disconnect and reconnect the cable. • Retry instrument initiation • If problem remains, check and refit other cables (controller cables and USB cable). • If problems still remain, contact Gyros.

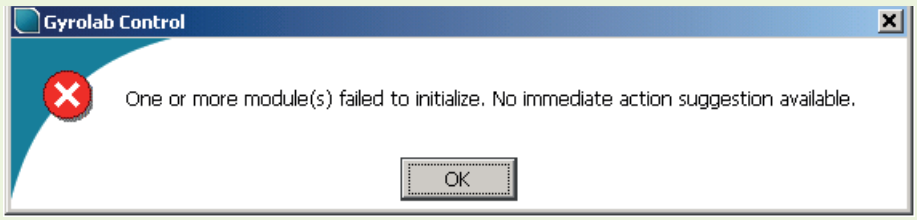

Gyrolab Control
Failed to move Robot or CD arm to home position, internal Galil error. No immediate action suggestion available.
OK

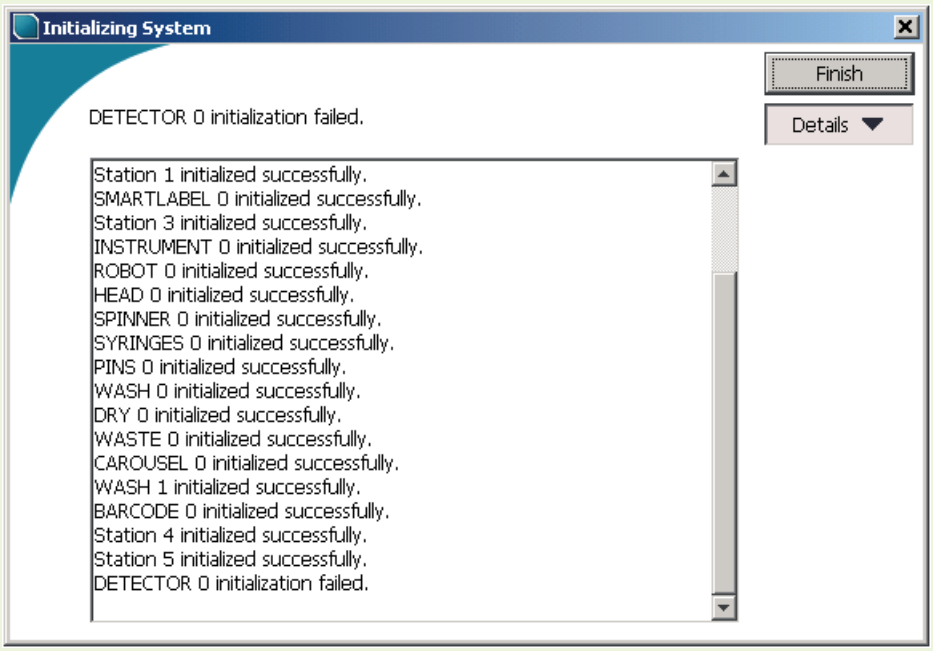
Examples of error messages: • Needles correlated error messages or that the instrument failures initialization, example in figure below. Possible cause: • Dislocated Controller cables	• Check Controller cable 2, refer to Chapter A2.3 • Disconnect and reconnect the cable. • Retry instrument initiation • If problem remains, check and refit other cables (controller cables and USB cable). • If problems still remain, contact Gyros.



© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

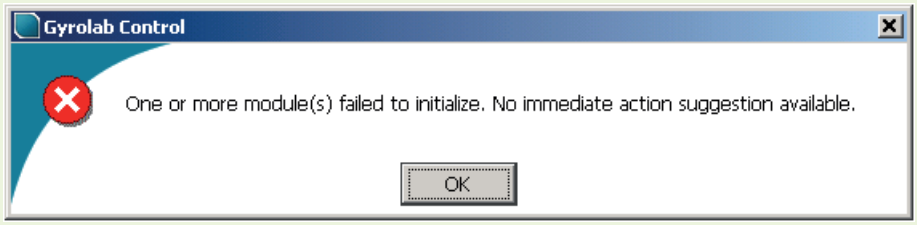
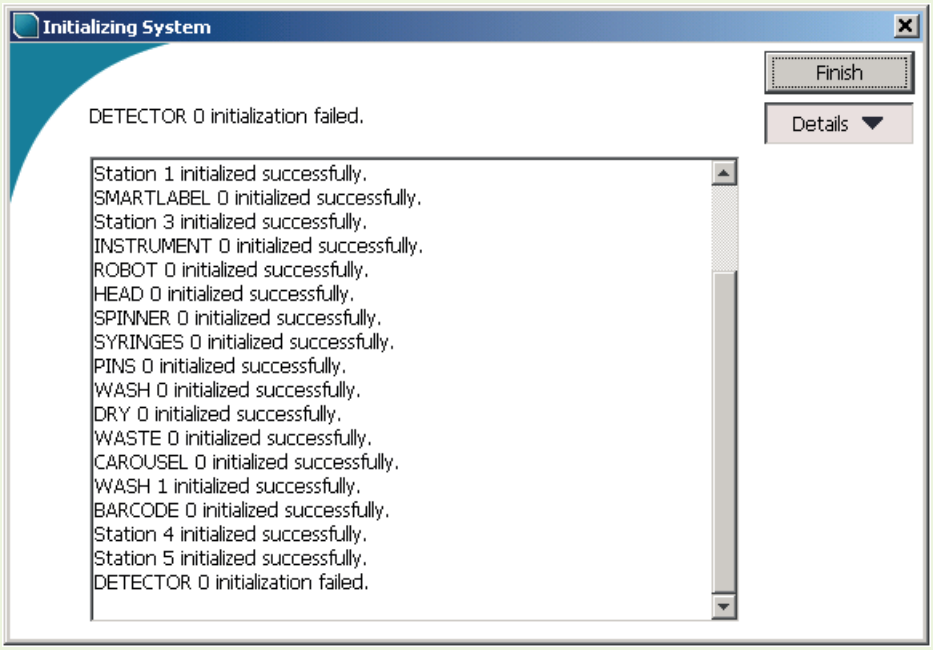
Error message/Possible cause	Action
Example of error message: • LIF correlated error messages, example in figures below. Possible cause: • Dislocated Controller cables	• Check Controller cable 3, Chapter A2.3. • Disconnect and reconnect the cable. • Retry instrument initiation • If problem remains, check and refit other cables (controller cables and USB cable). • If problems still remain, contact Gyros.





Example of error message: • Examples of error message below. Possible cause: • Dislocated Controller cables	• Check the connection between the computer and the instrument. • Restart the instrument and the computer. • If you cannot identify the problem, or if the problem remains, please contact Gyros for support.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Error message/Possible cause	Action
 	

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

G1.2 Instrument computer contact

If the instrument looses contact with the computer an ongoing run will continue until it has finished. The user interface on the computer will however not be able to follow the process in the instrument any longer, nor can it be used for unloading once the run has finished. This has to be done manually before a new run is started. Results from a run will be transferred to Gyrolab Results Database once the instrument gets contact with the computer again.

Lost contact with the instrument may occur in the following scenarios:

- USB cable removed or communication disturbed
- Computer restarted/shutdown
- Gyrolab Client Shutdown

G1.3 Gyrolab xPlore front panel LEDs

Problem	Action
If the Instrument Ready LED to the left on the front does not light up after a couple of minutes, the instrument has failed to start.	This might be resolved by turning off the instrument using the power switch on the rear of the instrument and try to start again.
If the LED on the Power button to the right on the front do not switch off after a couple of minutes when trying to power down the instrument the instrument has failed to power down.	This might be resolved by turning off the instrument using the power switch on the rear of the instrument and try to start again.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

G2 Software issues

This section contains information on how to diagnose and possibly solve problems related to software or software installation. If you cannot identify the problem, or if the problem remains, please contact Gyros for support.

G2.1 Gyrolab Control

Problem	Possible cause	Action
Sample list error message during Execute Run in Gyrolab Control	• Required information missing in the Sample List. • Information missing in Transfer and/or Reagent Lists (Custom Run only).	• Open Sample List and add any missing information. • Open list(s) and add any missing information.
Not possible to create a status report or result report of type .gyr	**Incorrect computer disc location**	The .gyr file must be saved on the local computer disc (usually the C: disc).
Results are not visible in Gyrolab Result Database	**The run has not completed the results yet. If a problem has occurred it might require manual action to get the results transferred.**	Restart the instrument and computer.

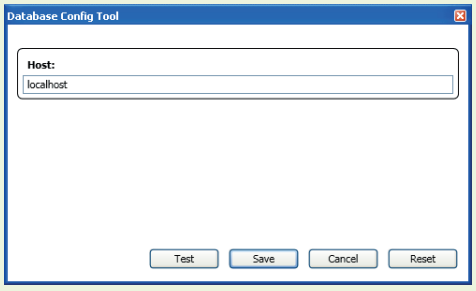
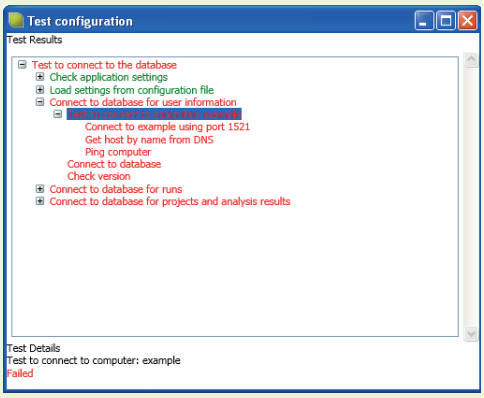
G2.2 Gyrolab Result Database Backup Manager

Problem	Action
Back-up of the Gyrolab Database using Gyrolab Database Backup Manager is scheduled in Windows. The Gyrolab Result Database Manager software opens, but does not automatically start the data back-up. It waits for a confirmation and someone has to physically press the button.	Ensure that the path to Gyrolab Result Database Backup Manager as used in the Windows scheduled task specifies the .exe file and does not include additional parameter.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

G2.3 Gyrolab Evaluator

Problem	Action

Installation and/or database communication problems	• Go to the folder C:\Program Files\Gyros\Gyrolab Evaluator N.N.N.N (software version), or the folder that was chosen for the installation, and start the application DatabaseConfigTool.exe:
	 
	
	• Click on **Test** to check that it is possible to connect to the database and that the communication with the database is working.
	 
	
	  • If the communication is working, all text in the dialogue is green.
	  • If there is a database communication problem, the text is colored red.
	  • To find out more, check messages on the innermost red nodes.
	• In the example shown above it was not possible to connect to the computer using the specified host name. This can be caused by a firewall on the instrument computer, or on the network where the office computer and the instrument computer is placed.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

G3 Application issues

This section contains information on how to diagnose and possibly solve problems related to immunoassay performance and results. If you cannot identify the problem, or if the problem remains, please contact Gyros for assistance.

G3.1 No response values are generated

Possible cause	Action
Was the CD positioned upside down?	Make sure the text on CD is readable after loading CD in Gyrolab instrument.
Was the LIF button in pressed-down position? (Only valid for Gyrolab instruments with a LIF button, refer to Chapter A2.2.1.)	Press LIF button. Initialize Gyrolab instrument 30 min before starting experiment. Check instructions in Chapter B2.1.
Were all samples. reagents and solutions placed in microplates according to Loading list?	Check instructions in Chapter B4.1.2 (Gyrolab xP) or Chapter B4.2.2. (Gyrolab xPlore)
Was the microplate foil applied on microplate according to recommendations?	Check that microplate foil is applied according to Microplate foil adapter instructions, supplied with the microplate foil.
Were all microplates correctly loaded in the microplate carousel?	Check instructions in Chapter B5.1.1.1 and Chapter B5.1.2.2.(Gyrolab xP) or Chapter B5.2.1.1 and Chapter B5.2.1.3.(Gyrolab xPlore)

G3.2 Unexpected appearance of standard curve

G3.2.1 Laboratory and instrument generated errors

Possible cause	Action
Were correct volumes of reagents and samples loaded in microplate wells?	Refer to Chapter B4.1.2 (Gyrolab xP) or Chapter B4.2.2. (Gyrolab xPlore) for details.
Were there air bubbles in microplate wells?	To remove air bubbles, centrifuge microplate at 3000 × g for two minutes. If bubbles still remain, increase time or speed until all bubbles are gone.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Possible cause	Action
Were there any air bubbles in the Syringe Pumps?	• Ensure that the degasser is working, refer to GL Degasser manual. • Inspect the syringes to ensure that there is no leakage. Refer to Gyrolab Instrument Guide. • To remove air bubbles, prime Gyrolab instrument, refer to Chapter B2.4. • If there still are air bubbles in the Syringe Pumps, remove the bubbles as described in Gyrolab Instrument Guide.

G3.2.2 Low response

Possible cause	Action
Were Unknown and Standard series samples handled and stored appropriately?	Frozen samples should be thawed on ice, vortexed and centrifuged before transfer to microplate wells, refer to Chapter B4.1.1.4 or Chapter B4.1.1.3 (Gyrolab xP) or Chapter B4.2.1.4 or Chapter B4.2.1.3 (Gyrolab xPlore) for details.
Where correct Rexxip buffers and solutions used according to Gyros recommendations?	Refer to Instruction For Use, supplied with the Rexxip buffer.
Are reagents freshly prepared? Where the reagents stored according to recommendations?	Refer to Chapter B1.1 and Chapter B1.2 for details.
If using a freshly labeled detection reagent: Is the optimal concentration used?	Titrate detection reagent concentration, refer to Chapter A3.4 for details.
If using a freshly labeled detection reagent: Was unbound labeling reagent sufficiently removed?	Remove unbound labeling reagent, refer to Chapter B1.2.
Is the optimal reagent pair used in the assay?	Further assay development and optimization may be needed, refer to Chapter A3.4 for details.

G3.2.3 Extensive variation

Possible cause	Action
Was the detection reagent centrifuged before use?	Refer to Chapter B1.2 for details.
Where the reagent stored according to recommendations?	Refer to Chapter B1.2 for details.
Was enough Wash Station Solution connected to the system?	Refer to Chapter B2.4 for details.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Possible cause	Action
Was the Wash Station pump moving during Run?	Prime Gyrolab instrument to ensure functionality of Wash Station pump. Refer to Chapter B2.4 for details.
Were there air bubbles in microplate wells?	To remove air bubbles, centrifuge microplate at 3000 × g for four min. If bubbles still remain, increase time or speed until all bubbles are gone.
Was enough volume of reagents and sample added to microplate wells?	Ensure that loaded volumes are according to volumes specified in Loading List.
Does the fluorescent signal image in Gyrolab Viewer show extensive variation?	Ensure that each CD contain Unknown/Standard series samples with a concentration larger than the limit of quantification for the assay and at least four structures with Unknown/Standard series samples with a response value of 0.5.
Was an old aliquot of detecting reagent used?	Use a fresh aliquot of detecting reagent.
Did sample to sample carryover interfere with results?	Gyrolab methods with extended wash procedures are available for analytes with specific biochemical properties. Contact Gyros for support.

G3.2.4 Detect result –Not OK in Gyrolab Evaluator result file

Possible cause	Action
• The fluorescence signal is saturated in the Fluorescence detector • The quantifier fails to calculate the response • The fluorescence signal generated from this particular structure in the CD microlaboratory is of poor quality.	• Results should be disregarded. • Adjust PMT setting.
Were serum or plasma samples analyzed in the Run?	Ensure that recommendations regarding sample preparation were followed. Serum and plasma samples should be thawed on ice, vortexed and centrifuged prior to dilution, refer to Chapter B4.1.1.4 (Gyrolab xP) or Chapter B4.2.1.4 (Gyrolab xPlore).
Was a partially used CD used in the Run?	Ensure to follow Instruction For Use for CDs regarding handling of a partly used CD.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

G3.2.5 Elevated background

Possible cause	Action
Was the detecting reagent stored and prepared according to recommendations?	Refer to Chapter B1.2 for details. In Figure 1 an example of elevated background caused by ageing of detection reagent during storage at +4 ºC is shown. The Figure shows a comparison of results using two different aliquots of detection reagent from the same labeling analyzed after storage for three months in fridge (crosses) and freezer (circles), respectively. There is a significantly elevated background after storage at +4 °C.
If using a freshly labeled detection reagent – is the optimal concentration used?	Titrate detection reagent concentration. Refer to Chapter A3.4.2 for details.
Were the correct Rexxip buffers used?	Refer to Chapter B4.1.1 (Gyrolab xP) or Chapter B4.2.1 (Gyrolab xPlore) for details.
Was enough wash solution added to the microplate wells?	Refer to Chapter B4.1.2 (Gyrolab xP) or Chapter B4.2.2 (Gyrolab xPlore) for details.
Did sample to sample carryover interfere with results?	Gyrolab methods with extended wash procedures are available for analytes with specific biochemical properties. Contact Gyros for support.

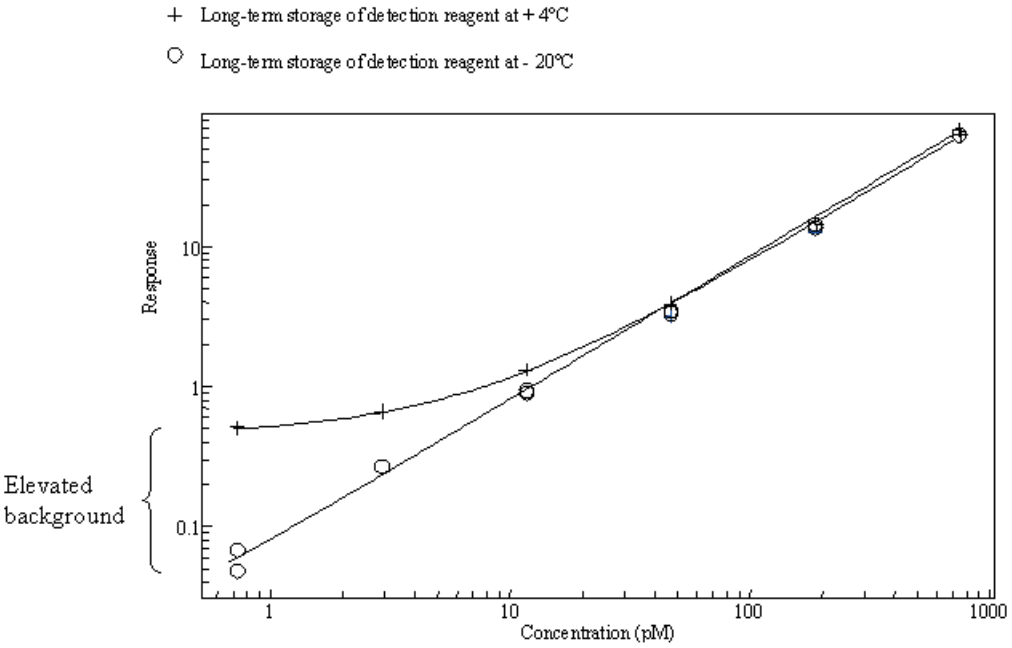


Figure 1: An example of elevated background caused by ageing of detection reagent during storage at +4 ºC.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

G3.3 Problems with outliers

Possible cause	Action
Contaminated spinner positions (CD and LIF)	Perform Clean surfaces in Gyrolab instrument on all surfaces. Refer to Gyrolab Instrument Guide. It is important also to wipe the LIF spinner position with a fresh lint free cloth without fluorescent material.

G3.4 Poor recovery of proteins after using Nanosep

Possible cause	Action
Protein interaction with Nanosep filter (Pall Life Sciences)	Surface pretreatment can in some situations increase recovery. Contact the supplier for instructions.

G3.5 Poor precision and bad reproducibility between runs

Possible cause	Action
Capture reagent dilution problems	Capture reagent dilution in Rexxip buffer might improve results. This is not applicable for antibodies. The recommended Rexxip buffers for this purpose are (in recommended order): Rexxip F, Rexxip A and Rexxip AN. PBS-T usually works well for monoclonal antibodies.

G3.6 Increased background in lower parts of the CD column

Possible cause	Action
Poor biotinylation. This may cause loss of unbiotinylated capture reagent during loading to the capture column and that an insufficient amount of biotinylated capture reagent being loaded. Unbound biotin may occupy binding sites on the capture column. This will dilute the density of specific capture reagent and usually lead to less efficient analyte capture and a broader fluorescent column profile.	Discard the biotinylated capture reagent batch and make a new biotinylation, refer to chapter Chapter B1.1.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

GYROLAB USER GUIDE

H Appendices

Contents

H1 Products, accessories and consumables H-3

H1.1 Gyros products H-3

H1.2 Recommended consumables H-4

H2 Custom Run workflow H-7

H2.1 Introduction to Custom workflow H-7

H2.2 Preparation of capture and detection reagents H-7

H2.3 Gyrolab instrument startup procedure H-7

H2.4 Experimental design H-8

H2.4.1 Create Sample List H-8

H2.4.2 Create Reagent List H-9

H2.4.3 Create Transfer List H-12

H2.4.4 Create or edit Run H-15

H2.5 Prepare Custom Run H-19

H2.6 Sample and reagents preparations H-20

H2.6.1 Capture reagent and detection reagent H-20

H2.6.2 Standard series and Calibration Controls H-20

H2.6.3 Unknown Samples and Quality Controls H-21

H2.6.4 Microplates H-21

H2.7 Start Run procedures H-21

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H2.8 After Run procedures and result export H-21

H2.9 Examples of run set-up and experiment mapping..... H-22

H2.9.1 Examples of experiment mapping for 1-CD runs H-22

H2.9.2 Examples of experiment mapping for multi- CD Runs..... H-25

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H1 Products, accessories and consumables

H1.1 Gyros products

Visit www.gyros.com for the latest updates on available products and services.

Product number	Name	Content
P0004424	Gyrolab Bioaffy 20HC	One piece (CD)
P0004180	Gyrolab Bioaffy 200	One piece (CD)
P0004253	Gyrolab Bioaffy 1000	One piece (CD)
P0020026	Gyrolab Mixing CD	One piece (CD)
P0003313	Microplate Foil	Pack of 50
P0004861	PCR Plate 96	Pack of 25
P0004820	Rexxip A	One piece (25 ml)
P0004821	Rexxip A-max	One piece (25 ml)
P0004822	Rexxip H	One piece (25 ml)
P0004823	Rexxip H-max	One piece (25 ml)
P0004994	Rexxip AN	One piece (25 ml)
P0004995	Rexxip AN-max	One piece (25 ml)
P0004996	Rexxip HN	One piece (25 ml)
P0004997	Rexxip HN-max	One piece (25 ml)
P0020033	Rexxip HX	One piece (25 ml)
P0020034	Rexxip HX-max	One piece (25 ml)
P0004824	Rexxip CCS	One piece (25 ml)
P0004825	Rexxip F	One piece (10 ml)
P0020027	Rexxip ADA	One piece (25 ml)
P0020096	Gyrolab Wash Buffer pH 11	Pack of 10 (10x10 gram)
P0005002	Gyrolab Functionality Check Kit	One piece (Kit)
P0003697	Microplate Foil Adapter	One piece
P0004955	Gyrolab User Licenses	Pack of 5
P0020028	Gyrolab Viewer	One piece (Software)
P0020025	Gyrolab ADA Software	One piece (Software)
P0005028	Gyrolab LIMS interface	One piece (Software)

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Product number	Name	Content
P0020006	Gyrolab Control Report	One piece (Software)
P0005016	Gyrolab Serial Dilution Analysis	One piece (Software)
P0000007	Syringe pump external tubing assembly (PEEK™)	One set of PEEK tubings (5 × 1 m) with fittings and connectors
P0000009	Wash tubing assembly	One set of wash tubing (2 × 1 m)
P0000010	Waste tubing assembly	One set of waste tubing (1 × 2 m)

H1.2 Recommended consumables

Product	Recommended supplier	Product no.
Ethanol 95%	–	–
Albumin, bovine serum, > 95% purity	Calbiochem	126615
Sodium azide	e.g. Aldrich	438456
Sodium chloride	e.g. Merck	106404
Sodium hypochlorite, CAS Number 7681–52–9	e.g. Aldrich	425044
Sodium dihydrogen phosphate NaH_2PO_4	e.g. Merck	106346
Sodium hydrogen phosphate Na_2HPO_4	e.g. Merck	106586
Tween 20	e.g. Merck	822184
Virkon S	DuPont	–
Syringe filter (disposable): 0.45 µm, 0.22 µm	–	–
Syringes: 10 ml, 50 ml	–	–
Alexa Fluor 647 Monoclonal Labeling Kit • Monoclonal antibody labeling kit optimized for labeling of 100 µg antibodies and proteins >30 kDa.	Molecular Probes	A-20186
Alexa Fluor 647 Microscale Protein Labeling Kit • Protein labeling kit optimized for labeling of 20–100 µg proteins 10–150 kDa.	Molecular Probes	A30009
Dylight™ 649 Microscale Antibody Labeling Kit • Antibody labeling kit optimized for labeling of 100 µg antibodies and proteins 50–150 kDa	Thermo Scientific	53051
EZ-Link Sulfo-NHS-LC-Biotin • 8 × 1 mg microtubes (No-weight format)	Thermo Scientific	21327
EZ-Link Sulfo-NHS-LC-Biotin • 100 mg	Thermo Scientific	21335

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Product	Recommended supplier	Product no.
Nanosep 30K OMEGA Centrifugal Devices Note that the size of the filter in the spin column depends on the size of the reagent. Nanosep centrifugal devices exist in 3K, 10K, 30K and 100K.	Pall Life Sciences	OD030C34
Protein Desalting Spin Columns	Thermo Scientific	89849

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H2 Custom Run workflow

This chapter it is describes how to perform immunoassyas in Gyrolab Instrument using the **Custom Run** workflow (design type). Refer to Chapter A3.1 for recommendations of when to use which Run design type.

Only instructions that are unique for Custom Run is included in this chapter. For the parts of the workflow that are identical between Custom Run and Wizard Run, refer to relevant section in Chapter B.

H2.1 Introduction to Custom workflow

The Custom Run workflow is designed for maximal flexibility and allows the user to customize what samples are quantified towards what reagent set. Custom Run can be used when non-standard transfer from microplates to CD microlaboratories is required or when a variation of replicates for different samples and standard points for example during assay development is required.

No Loading List is generated during experiment set-up. Transfer and Reagent Lists are required to define a Custom Run.

H2.2 Preparation of capture and detection reagents

Please refer to Chapter B1.

H2.3 Gyrolab instrument startup procedure

Please refer to Chapter B2.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

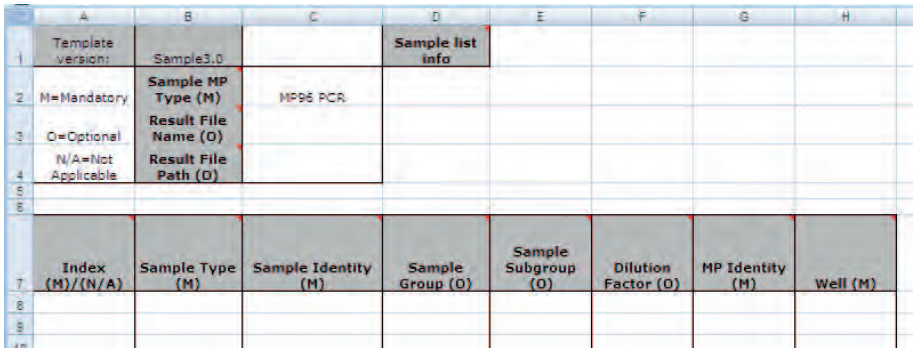
H2.4 Experimental design

Chapter H2.9 contains detailed information and examples on how to prepare Sample, Reagent and Transfer lists to achieve intended mapping of samples against standard curves.

H2.4.1 Create Sample List

The Sample List is designed to transfer sample information to Gyrolab Control. Gyros provides a **Sample List template** in Microsoft Excel format.

Step	Action
1.	Open the **Sample List Template** `Sample_list_template.xls` found in `C:\ProgramData\Gyros\Gyrolab\Templates\Lists`
2.	From row 8 and below, one row in the Sample list represents one sample. Columns labelled (M) are mandatory, columns labelled (0) are optional and columns labelled (N/A) are not used.



	A	B	C	D	E	F	G	H
1	Template version:	Sample3.0		Sample list info				
2	M=Mandatory	Sample MP Type (M)	MP96 PCR					
3	O=Optional	Result File Name (O)						
4	N/A=Not Applicable	Result File Path (O)						
5								
6								
7	Index (M)/(N/A)	Sample Type (M)	Sample Identity (M)	Sample Group (O)	Sample Subgroup (O)	Dilution Factor (O)	MP Identity (M)	Well (M)
8								
9								

Figure H2-1: Sample list template

NOTE: ***Cells with a red mark in the upper right hand corner have a comment attached. The comment is a description of the information to be included in the column/cell.***

3.	Fill in sample information according to Table B3-1 in Chapter B3.1.3 (Gyrolab xP) or Table B3-3 in Chapter B3.2.3 (Gyrolab xPlore). For multi-CD runs: If designing multiple-CD Run where a Standard series/Unknown/Calibration Control/Quality Control sample is repeated on different CDs it must be placed in separate wells in the reagent microplate (and on separate rows in the Sample list) in order to avoid evaporation during the run. The number of wells for each Standard series/Unknown/Calibration Control/Quality Control sample shall correspond to the number of CDs in the Run on which the sample should be used on. Each row in the Sample list must have unique sample identity. Refer to examples in Chapter H2.9.2.
4.	Click **File:Save As** to save the Sample list in a folder accessible by the Gyrolab computer. ***NOTE:*** ***Do not save the file in the*** `C:\ProgramData\Gyros\Gyrolab\Templates\Lists` ***folder. This folder should be kept for list templates only.***
5.	Click **File:Close** to close the Sample list.

TIP: ***Print the Sample List and use when preparing sample microplates.***

TIP: ***Quality Control samples are valid only in the reagent list.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H2.4.2 Create Reagent List

The Reagent List contains information about the solutions in the reagent plate, such as type of liquid, concentration (for Standard series samples), dilution factor etc. The Reagent List template must be edited for each new set of reagents used for each new Run.

Step Action

1. Open the **Reagent List Template** Reagent_list_Template.xls found in `C:\ProgramData\Gyros\Gyrolab\Templates\Lists`.

2. From row 3 and below, one row in the Reagent list represents one reagent. Columns labelled (M) are mandatory, columns labelled (0) are optional and columns labelled (N/A) are not used.

	A	B	C	D	E	F	G
1	MP Type (M)	MP96 PCR	M=Mandatory	O=Optional			Reagent list info
2	Name (M)	Type (M)	Concentration (M)/(N/A)	Unit (M)/(N/A)	Dilution Factor (O)	MP Name (M)	Well (M)
3							
4							
5							
6							

Figure H2-2: Reagent list template

> ***NOTE:*** ***Cells with a red mark in the upper right hand corner have a comment attached. The comment is a description of the information to be included in the column/cell.***

3. Fill in reagent information according to Table H2-1.

4. Click **File:Save As** to save the Reagent list in a folder accessible by the Gyrolab computer.

   Do not save the file in the `C:\ProgramData\Gyros\Gyrolab\Templates\Lists` ***folder. This folder should be kept for list templates only.***

5. Click **File:Close** to close the Reagent list.

Reagent List item	Mandatory/ Optional	Information
MP type Cell B1	Mandatory	Type of microplate ***NOTE:*** ***Use only microplates recommended by Gyros, that is MP96 PCR.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Reagent List item	Mandatory/ Optional	Information
Name Column A	Mandatory	This name is the identity of the reagent and must correspond to the name specified in the transfer list. The name of the reagent is defined by the user. It is case sensitive, so take care to copy it exactly. Enter each reagent name on a new row (Check cell A2 **Name** for list of allowed characters). For multi-CD runs: If designing multiple-CD Run where a Standard series/Unknown/Calibration Control/Quality Control -sample is repeated on different CDs it must be placed in separate wells in the reagent microplate (and on separate rows in the Reagent list) in order to avoid evaporation during the run. The number of wells for each Standard series/Unknown/Calibration Control/Quality Control sample shall correspond to the number of CDs in the Run on which the sample should be used on. Each row in the Reagent list must have unique name. Refer to examples in Chapter H2.9.2. It is possible to group reagent combination together for subsequent data analysis by use of a common Experiment name, refer to Chapter H2.4.4 and Chapter for details.
Type Column B	Mandatory	Enter reagent type or sample type for reagents and samples. (For more information on sample types, refer to Chapter A3.3.2): • RR = Reagent regular (wash etc.) • RB = Reagent biomolecule (capture or detection reagent) • STD = Standard series • CC = Calibration Control • BL = Blank • QC = Quality Control
Concentration Column C	Mandatory N/A	Enter the concentration for each reagent. • Mandatory for Standard series (STD), Blank (BL), Calibration Control (CC) and Quality Control (QC). • Not applicable for Reagent regular (RR) and Reagent biomolecule (RB) reagents • For Quality Control (QC) samples enter the undiluted concentration if diluted. Enter the dilution factor in column E.
Unit Column D		Enter the unit of concentration for example pM, mg/ml. • Mandatory for Standard series (STD), Blank (BL), Calibration Control (CC) and Quality Control (QC). • Not applicable for Reagent regular (RR) and Reagent biomolecule (RB) reagents

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Reagent List item	Mandatory/ Optional	Information
Dilution Column E	Optional	Enter the dilution factor for Quality Control (QC) samples. Undiluted samples have dilution factor = 1. Dilution values must be 1 or higher. If nothing is entered the default value is =1.
MP Name Column F	Mandatory	Identity of microplate where the reagent or standard solutions is located.
Well Column G	**Mandatory**	Enter the positions of reagents and standard solutions in the microplate, for example A1, A2. For optimal liquid transfer use the same liquid in rows with the same letter (8 well rows). • If the MP Type is given, and the MP Name and Well columns are completed, this information will appear in the **Execute Run** screens for loading Gyrolab instrument.

Table H2-1: Specification for Reagent list

TIP: ***Print the Reagent List and use when preparing reagent microplates.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H2.4.3 Create Transfer List

A Transfer List is required for Custom Run and describes how samples and reagents are transferred to defined microstructures in the CD microlaboratory. The Transfer List template must be edited to match the specific CD to be used. A transfer list can be used for one specific Run. There are several templates available for different types of assays. For each assay type one template is provided for running 1 CD and another template for running up to 5 CD microlaboratories.

Step Action

1. Open ta suitable **Transfer List Template** found in `C:\Program-Data\Gyros\Gyrolab\Templates\Lists`.

2. From row 3 and below, one row represents one inlet on a CD and column from column D and further represent transfer operations in the method. The columns labelled M are mandatory and the columns labelled O are optional.

A	B	C	D	E	F	G	H
Use Exact Mapping (M)	No	**Transfer list info**	**CD Type (O)**	Gyrolab Bioaffy 1	M=Mandatory	O=Optional	N/A=Not Applicable
Segment (M)	**Structure (M)**	**Inlet (M)**	**Op_Capture reagent addition**	**Op_Analyte addition**	**Op_Detection reagent addition**		
1	Common left	Common inlet					
1	1	Structure inlet					
1	2	Structure inlet					
1	3	Structure inlet					
1	4	Structure inlet					
1	5	Structure inlet					
1	6	Structure inlet					
1	7	Structure inlet					
1	8	Structure inlet					
2	Common left	Common inlet					
2	1	Structure inlet					
2	2	Structure inlet					
2	3	Structure inlet					
2	4	Structure inlet					
2	5	Structure inlet					
2	6	Structure inlet					
2	7	Structure inlet					

Figure H2-3: Transfer List template

NOTE: ***Cells with a red mark in the upper right hand corner have a comment attached. The comment is a description of the information to be included in the column/cell.***

NOTE: ***The number of columns in the template depends on the number of customized transfers in the used Method.***

3. Fill in transfer information according to Table H2-2.

4. Click **File:Save As** to save the Transfer list in a folder accessible by the Gyrolab computer.

   NOTE: ***Do not save the file in the*** `C:\ProgramData\Gyros\Gyrolab\Templates\Lists` ***folder. This folder should be kept for list templates only.***

5. Click **File:Close** to close the Transfer list.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Transfer List item	information
Use Exact Mapping **Cell B1**	Specifies if Exact mapping will be used. This value can be **Yes** or **No**. • Yes – the number of samples entered must match the number stated in the Sample List. • No – it is possible to enter the same or a lower number of samples than the number stated in the Sample List.
CD type Cell E1	Specifies the CD type.
Segment Column A	The segment numbers each refer to a specific segment on a CD microlaboratory. The segment are used in order. Segment 1 refers to the first available segment on the CD, segment 2 means the second available segment etc. • For Bioaffy 20 HC and Bioaffy 200 CDs (that have 14 segments on each CD): If more than one CDs are used, segment 15 means the first segment on the second CD, segment 16 means the second segment on the second Bioaffy CD microlaboratory etc. • For Bioaffy 1000 CDs (that have 12 segments on each CD): If more than one CDs are used, segment 13 means the first segment on the second CD, segment 14 means the second segment on the second Bioaffy CD microlaboratory etc. • If partly used CDs are included in the Run, there are less than 14 (12 for Bioaffy 1000) segments available on those CDs and the numbering of segments will be different than normal.
Structure Column B	Structures are either common structures (named **Common left** or **Common right**) or individual structures (**1**–**8**). For each segment, there are one Common left, one Common right and eight individual structures. • All operations will begin in the first microstructure of the first unused segment of the CD. • Common left is used for adding liquid to all structures in one segment, starting from the left. • Common right is used for adding liquid to all structures in one segment, starting from the right. • The microstructure numbers 1, 2, 3 indicate individual structures in a segment.
Inlet Column C	Inlet specifies where samples and reagents are applied on the CD microlaboratory: either to a common inlet (common distribution channel) or to a structure inlet (individual microstructure).

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Transfer List item	information
Op_Capture reagent addition Column D	First operation in the method. The name must be written as Op_<your customized transfer name from method> for example Op_Capture reagent addition. Naming is case sensitive. The entries here are the names from the reagent list, or a number for example #1 if it comes from a Sample List. This specifies where the reagent or sample will be placed on the CD, and in which operation. ***NOTE: Methods and transfer lists are connected through the Run. The order of operations in the transfer list must follow the same order as the operations in the method. For each customized transfer operation in the method, one column is needed in the Transfer list. Contact Gyros for more details on method design.***
Op_Analyte addition Column E	Second operation in the method. The name must be written as Op_<your customized transfer name from method> for example Op_Analyte addition. Naming is case sensitive. The entries are the reagent or sample name from the Reagent list or Sample list. This specifies where the reagent or sample will be placed on the CD, and in which operation it will be used. ***NOTE: It is crucial that all replicates of the same Standard series/ Unknown/Calibration Control/Quality Control sample are placed on the same CD.***
Op_Detect reagent addition Column F	Third operation in the method to be performed. The name must be written as Op_<your customized transfer name from method> for example Op_Detection reagent addition. Naming is case sensitive. The entries are the reagent or sample name from the Reagent list or Sample list. This specifies where the reagent or sample will be placed on the CD, and in which operation it will be used.
Op_ Column G	Forth operation in the method to be performed. The name must be written as Op_<your customized transfer name from method> for example Op_Detection reagent addition. Naming is case sensitive. The entries are the reagent or sample name from the Reagent list or Sample list. This specifies where the reagent or sample will be placed on the CD, and in which operation it will be used.

Table H2-2: Specification for Transfer list

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H2.4.4 Create or edit Run

There are three options available when setting up a new Run:

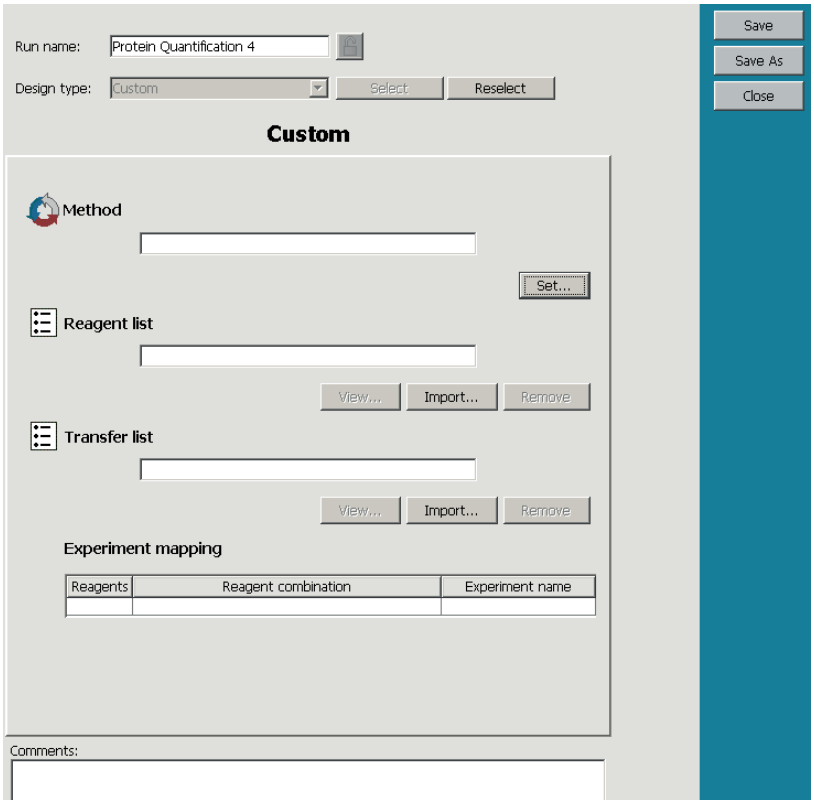
- Create a new Run, proceed with Chapter H2.4.4
- Edit an existing Run (use when similar but not identical experiment design is wanted), proceed with Chapter H2.4.4
- Use an existing Run (use when identical experiment design is wanted), go to Chapter H2.5.

Step	Action
1.	Click **Design Run** on the Main menu. The **Design Run** screen appears.

2.
- To create a new Run, click **New**. Give the Run a name.
- To edit an existing Run, browse to locate the desired Run, select the Run and click **Open**. Follow instructions below from step 4 and edit items to be changed and leave the other items unedited.

3. Select **Custom Run** in the **Design type:** list and click **Select** button.

Custom Run panel can now be seen.

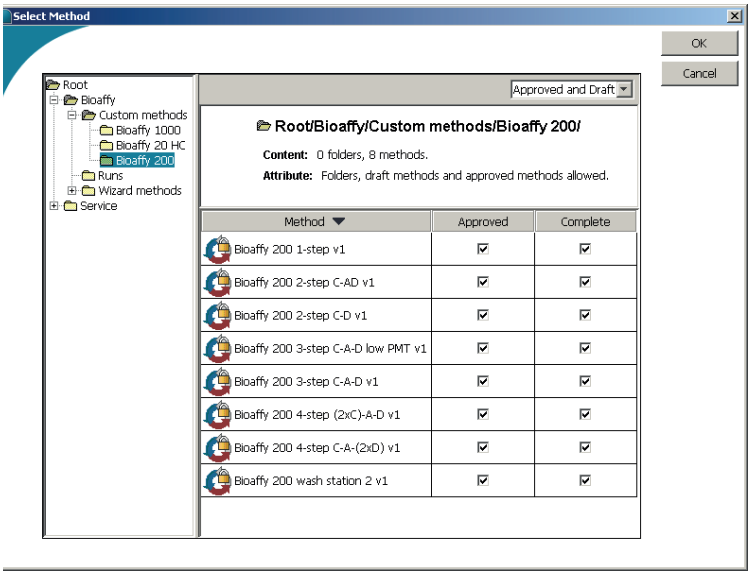


© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

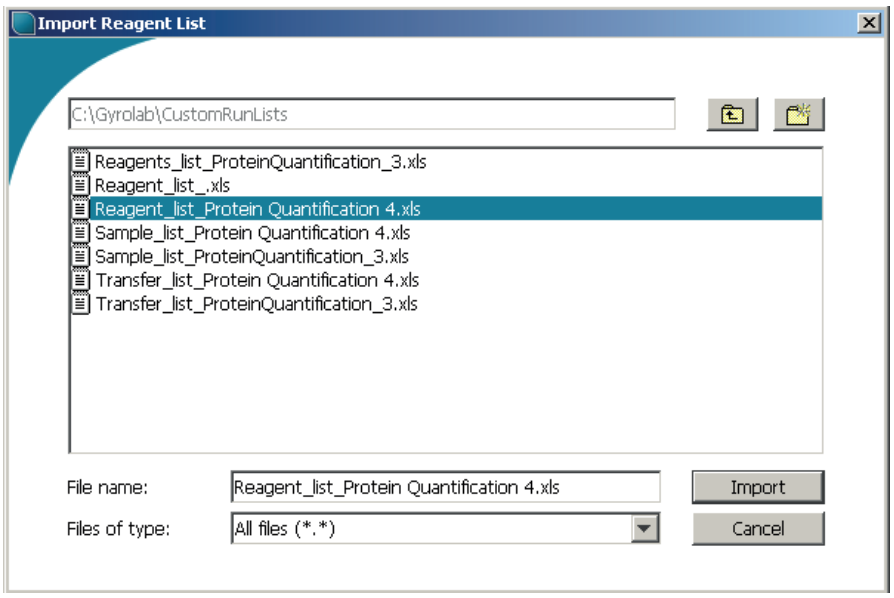
4. Click **Set** to select **Method**.

The **Select Method** dialog is opened. Select method and click **OK**.



5. Click **Import** under **Reagent List** and the **Import Reagent List** dialog opens.

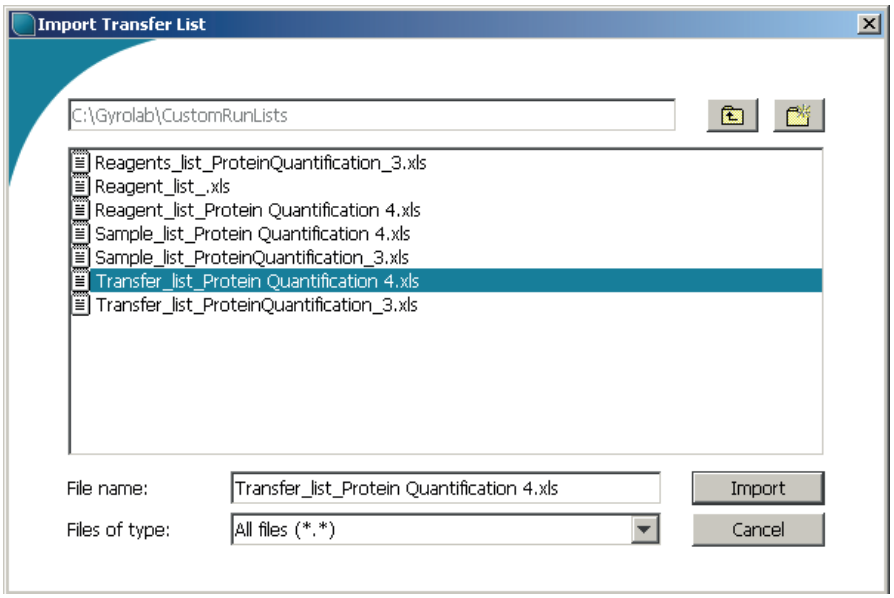
Browse to locate the desired Reagent list file, prepared in Chapter H2.4.2 and click **Import**.



In **Custom Run** panel:

- Click **View** button to view the contents of the imported Reagent List file. Click **Close** after viewing.
- Click **Remove** button to delete the imported Reagent list.

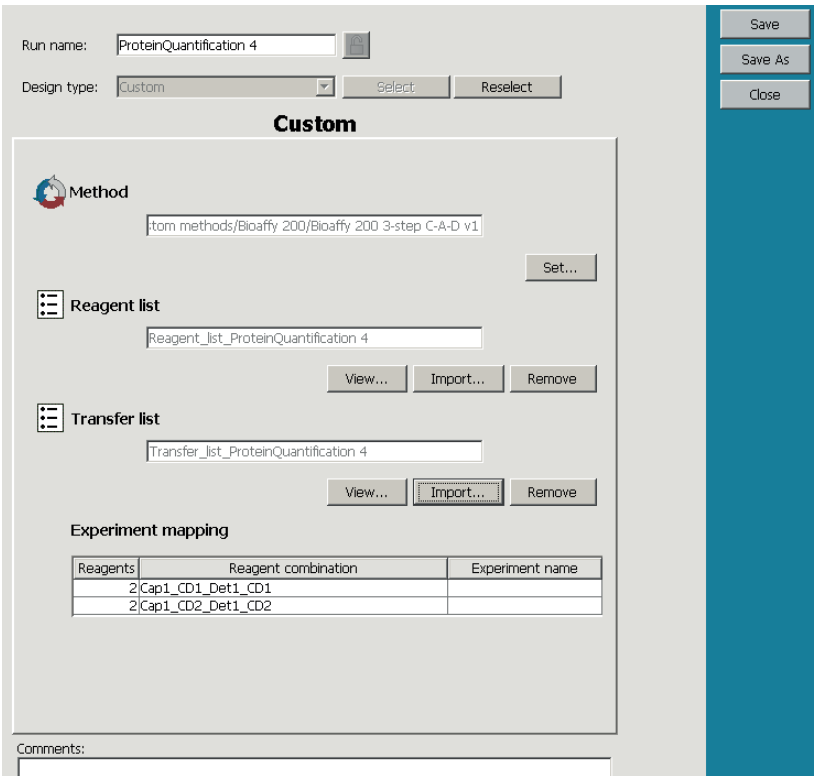
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action
6.	Click **Import** under **Transfer List**, the **Import Transfer List** dialog appears. Browse to locate the desired Transfer list file, prepared in Chapter H2.4.3 and click **Import**.  In **Custom Run** panel: • Click **View** button to view the contents of the imported Transfer List file. Click **Close** after viewing. • Click **Remove** button to delete the imported Transfer list.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Step	Action

7. After selecting Method, Reagent list and Transfer list, the **Experiment mapping** section lists information on **Reagent combinations**.



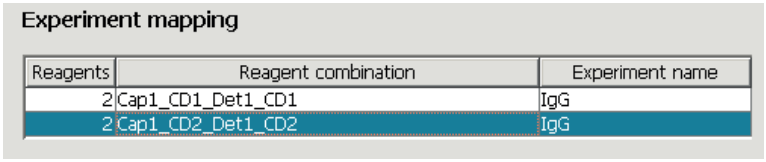
For multi-CD runs, reagents must be placed in unique microplate wells (one per CD) and have unique identities, even if it is the same reagent. Data analysis in Gyrolab Evaluator are based on which reagents (**Reagent combination**) that are used for the specific sample.

It is possible to group sample made with identical reagents but with different reagents names by giving them a common **Experiment name**. Gyrolab Evaluator will analyze all samples with a common **Experiment name** together if it is present. If not present the **Reagent combination** will be used to group samples.

Another reason for using an Experiment name is that it is possible to use a simple informative name, for example IgG.

To group reagent combinations for subsequent data analysis:

- Enter identical names in the **Experiment name** field for regent combinations to be grouped together.



8.

- To save a new Run, click **Save**. Browse to select folder and click **Save**.
- To save an edited Run, click **Save as**. Give the Run a name, browse to select folder and click **Save**. If **Save** is clicked the original Run will be lost.

NOTE: ***If changes are made to the transfer and/or reagent lists, they must be re-imported to the Run to be performed.***

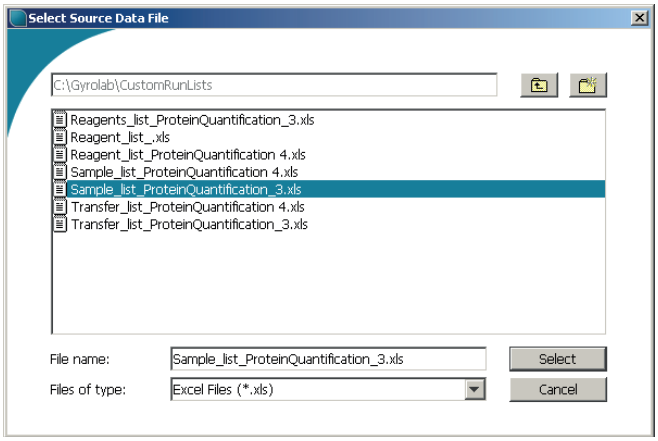
© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H2.5 Prepare Custom Run

Step	Action
1.	Click **Execute Run** on the Main menu.
2.	Browse and select desired **Run** from the list and click **OK**.

Click **Sample List File**.

3.	Browse and select desired Sample List and click **Select**.



4.	**Number of samples** is displayed and the Sample List status is set to Loaded. Click **OK**.
5.	A screen with **Targets** tab and **Reports** tab is opened. Refer to Chapter B3.1.4 for settings.
6.	Click **OK**.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H2.6 Sample and reagents preparations

This chapter describes preparation of capture and detection reagents, standard sample series, Calibration Controls, Quality Controls and unknown samples as well as the distribution of samples and reagents in microplates. For preparing reagents for a multi CD Run, refer to Chapter H2.9.2 for details.

The following solutions and reagents are required:

- PBS-T (for recipe, refer to Chapter E1.2)
- Capture and Detection reagents
- Standard Protein
- Rexxip buffer (Refer to Product information sheet for Rexxip buffers for recommendations on buffer selection)

H2.6.1 Capture reagent and detection reagent

Prepare capture reagent and detection reagent according to Chapter H2.6.1 and Chapter H2.6.2 respectively. For minimum required reagent volumes, use formula below:

- `Reagent volume = (2.5 µl × Number of segments) + 15 µl`

For correct number of segments, refer to Transfer list (Chapter H2.4.3).

NOTE: ***In multiple-CD Runs reagents that are used on more than one CD must be placed in different microplate wells, one per CD, refer to Chapter H2.4.2. Calculate minimum required volume per well using the formulas above.***

H2.6.2 Standard series and Calibration Controls

Prepare Standard series and Calibration Controls according to Chapter H2.6.2. For minimum required sample volumes, use formulas below:

For **Bioaffy 20 HC and Bioaffy 200**:

- `Standard volume = (0.5 µl × Number of replicates) + 2.5 µl`

For **Bioaffy 1000**:

- `Number of replicates is 8 or less:`
  `Standard volume = (2.5 µl × Number of replicates) + 5.0 µl`
- `Number of replicates is 8 or more`
  `Standard volume = (2.5 µl × Number of replicates) + 10.0 µl`

For correct number of replicates, refer to Transfer list prepared in Chapter H2.4.3.

NOTE: ***In multiple-CD Runs, samples that are used on more than one CD must be placed in different microplate wells, one per CD, refer to Chapter H2.4.2. Calculate minimum required volume per well using the formulas above.***

NOTE: ***Calibration Controls can be used in multiple-CD runs and are selected points in the Standard series. When calibration Controls are used, one must prepare extra volume of Standard series samples to ensure that the volume is sufficient for both the Standard series sample and Calibration Control. It is very important that the Standard series and Calibration Control samples are from the identical Standard series dilution.***

NOTE: ***If more than 41 replicates are used on a Bioaffy 1000 CD the sample liquid must be divided into more than one well.***

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H2.6.3 Unknown Samples and Quality Controls

Prepare Standard series and Calibration Controls according to Chapter H2.6.3. For minimum required sample volumes, use formula below:

For **Bioaffy 20 HC and Bioaffy 200**:

- `Sample volume = (0.5 µl × Number of replicates) + 2.5 µl`

For **Bioaffy 1000**:

- `Number of replicates is 8 or less:`
  `Sample volume = (2.5 µl × Number of replicates) + 5.0 µl`
- `Number of replicates is 8 or more`
  `Sample volume = (2.5 µl × Number of replicates) + 10.0 µl`

NOTE: ***In multiple-CD Runs, samples that are used on more than one CD must be placed in different microplate wells, one per CD, refer to Chapter H2.4.1. Calculate minimum required volume per well using the formulas above.***

NOTE: ***If more than 41 replicates are used on a Bioaffy 1000 CD the sample liquid must be divided into more than one well.***

H2.6.4 Microplates

Prepare microplates according to Chapter B4.2.2.

Prepare reagent microplate:

Reagent microplate contains:

- Capture reagent
- Detection reagent
- Standard series samples including blank samples
- Quality Control samples
- Calibration Control samples

The volumes and microplate positions are specified in the **Reagent List** Chapter H2.4.2 and **Transfer List**, prepared in Chapter H2.4.3.

Prepare sample microplate:

Sample microplate contains:

- Unknown samples

Transfer the samples, as prepared in Chapter H2.6.3, to wells in the sample microplate according to the order stated in the Sample List prepared in Chapter H2.4.1.

H2.7 Start Run procedures

Please refer to Chapter B5.

H2.8 After Run procedures and result export

Please refer to Chapter B6.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

H2.9 Examples of run set-up and experiment mapping

Evaluation of results of samples of different types (Standard series/Unknown/Calibration Control/Quality Control) in Gyrolab Evaluator are based on which reagents (**Reagent combination**) that are used for the specific sample.

By using the option of **Experiment mapping** (refer to Chapter H2.5) it is possible to group sample analyses made by identical reagents but with different reagents names by giving them a common **Experiment name**. Gyrolab Evaluator will analyze all samples with a common **Experiment name** together if it is present. If not present the **Reagent combination** will be used.

The following chapters provide examples to high-light how sample naming and experiment mapping will affect sample grouping during data analysis in Gyrolab Evaluator

H2.9.1 Examples of experiment mapping for 1-CD runs

Four examples of run set-up for 1-CD runs are provided.

Example 1: One Reagent combination and one standard curve

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioaffy	M=Mandatory	O=Optional	N/A=Not Applicable
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition		
1	Common left	Common inlet	Capture		Detection		
1	1	Structure inlet		Blank			
1	2	Structure inlet		Standard_1			
1	3	Structure inlet		Standard_2			
1	4	Structure inlet		Standard_3			
1	5	Structure inlet		Standard_4			
1	6	Structure inlet		Standard_5			
1	7	Structure inlet		Standard_6			
1	8	Structure inlet		Standard_7			
2	Common left	Common inlet	Capture		Detection		
2	1	Structure inlet		Blank			
2	2	Structure inlet		Standard_1			
2	3	Structure inlet		Standard_2			
2	4	Structure inlet		Standard_3			
2	5	Structure inlet		Standard_4			
2	6	Structure inlet		Standard_5			
2	7	Structure inlet		Standard_6			
2	8	Structure inlet		Standard_7			

Figure 9: One calibration reference and one standard curve in transfer list

A Run using this transfer list will generate following in Gyrolab Evaluator:

- One **Reagent combination**: Capture_Detection.
- One standard curve in duplicates.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Example 2: Two Reagent combinations

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioaffy	M=Mandatory
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
1	Common left	Common inlet	Capture_1		Detection_1
1	1	Structure inlet		Curve_1_Blank	
1	2	Structure inlet		Curve_1_Standard_1	
1	3	Structure inlet		Curve_1_Standard_2	
1	4	Structure inlet		Curve_1_Standard_3	
1	5	Structure inlet		Curve_1_Blank	
1	6	Structure inlet		Curve_1_Standard_1	
1	7	Structure inlet		Curve_1_Standard_2	
1	8	Structure inlet		Curve_1_Standard_3	
2	Common left	Common inlet	Capture_1		Detection_1
2	1	Structure inlet		#1	
2	2	Structure inlet		#2	
2	3	Structure inlet		#3	
2	4	Structure inlet		#4	
2	5	Structure inlet		#1	
2	6	Structure inlet		#2	
2	7	Structure inlet		#3	
2	8	Structure inlet		#4	
3	Common left	Common inlet	Capture_2		Detection_2
3	1	Structure inlet		Curve_2_Blank	
3	2	Structure inlet		Curve_2_Standard_1	
3	3	Structure inlet		Curve_2_Standard_2	
3	4	Structure inlet		Curve_2_Standard_3	
3	5	Structure inlet		Curve_2_Blank	
3	6	Structure inlet		Curve_2_Standard_1	
3	7	Structure inlet		Curve_2_Standard_2	
3	8	Structure inlet		Curve_2_Standard_3	
4	Common left	Common inlet	Capture_2		Detection_2
4	1	Structure inlet		#1	
4	2	Structure inlet		#2	
4	3	Structure inlet		#5	
4	4	Structure inlet		#6	
4	5	Structure inlet		#1	
4	6	Structure inlet		#2	
4	7	Structure inlet		#5	
4	8	Structure inlet		#6	

Figure 10: Example of two **Reagent combinations** in the transfer list

A Run using this transfer list will generate following in Gyrolab Evaluator:

- Two different **Reagent combinations**:
  - Capture_1_Detection_1
  - Capture_2_Detection_2
- Two standard curves in duplicates. One for each **Reagent combination**.
- Samples 1 and 2 will be quantified against both standard curves 1 and 2 (**Reagent combination** 1= Capture_1_Detection_1 and **Reagent combination** 2= Capture_2_Detection_2)
- Samples 3 and 4 will be quantified against curve 1 (**Reagent combination** = Capture_1_Detection_1)
- Samples 5 and 6 will be quantified against curve 2 (**Reagent combination** = Capture_2_Detection_2)

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Example 3: Two different Standard series and one Reagent combination

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioaffy	M=Mandatory
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
1	Common left	Common inlet	Capture		Detection
1	1	Structure inlet		Curve1_Blank	
1	2	Structure inlet		Curve1_Standard_1	
1	3	Structure inlet		Curve1_Standard_2	
1	4	Structure inlet		Curve1_Standard_3	
1	5	Structure inlet		Curve1_Blank	
1	6	Structure inlet		Curve1_Standard_1	
1	7	Structure inlet		Curve1_Standard_2	
1	8	Structure inlet		Curve1_Standard_3	
2	Common left	Common inlet	Capture		Detection
2	1	Structure inlet		Curve2_Blank	
2	2	Structure inlet		Curve2_Standard_1	
2	3	Structure inlet		Curve2_Standard_2	
2	4	Structure inlet		Curve2_Standard_3	
2	5	Structure inlet		Curve2_Blank	
2	6	Structure inlet		Curve2_Standard_1	
2	7	Structure inlet		Curve2_Standard_2	
2	8	Structure inlet		Curve2_Standard_3	

Figure 11: Two different Standard series with, for example different standard preparations/dilutions, but only one **Reagent combination** will generate one standard curve

A Run using this transfer list will generate following in Gyrolab Evaluator:

- One **Reagent combination**: Capture_Detection.
- One standard curve in 4 replicates.

NOTE: Even though the Standard series have been given different names in the transfer list, see figure for current example, they will be analyzed against the same **Reagent combination** *and thus they will be evaluated as replicates of the same curve. In order to generate two different standard curves (for example with different standard preparations/dilutions) two different* **Reagent combination** *are needed, see figure for example 4.*

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Example 4: Two different Standard series and two Reagent combinations

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioaffy	M=Mandatory
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
1	Common left	Common inlet	Capture_Curve_1		Detection_Curve_1
1	1	Structure inlet		Curve_1_Blank	
1	2	Structure inlet		Curve_1_Standard_1	
1	3	Structure inlet		Curve_1_Standard_2	
1	4	Structure inlet		Curve_1_Standard_3	
1	5	Structure inlet		Curve_1_Blank	
1	6	Structure inlet		Curve_1_Standard_1	
1	7	Structure inlet		Curve_1_Standard_2	
1	8	Structure inlet		Curve_1_Standard_3	
2	Common left	Common inlet	Capture_Curve_2		Detection_Curve_2
2	1	Structure inlet		Curve_2_Blank	
2	2	Structure inlet		Curve_2_Standard_1	
2	3	Structure inlet		Curve_2_Standard_2	
2	4	Structure inlet		Curve_2_Standard_3	
2	5	Structure inlet		Curve_2_Blank	
2	6	Structure inlet		Curve_2_Standard_1	
2	7	Structure inlet		Curve_2_Standard_2	
2	8	Structure inlet		Curve_2_Standard_3	

Figure 12: Two different Standard series, with for example different standard preparations/dilutions, with two different **Reagent combinations** will generate two standard curves

A Run using this transfer list will generate following in Gyrolab Evaluator:

- Two **Reagent combination**:
  - Capture_curve 1_Detection_curve 1
  - Capture_curve 2_Detection_curve 2
- Two standard curves in duplicates. One for each **Reagent combination**.

H2.9.2 Examples of experiment mapping for multi- CD Runs

Three examples for set-up of multi-CD Runs are provided.

NOTE: ***In the following examples Transfer Lists where only transfers to segments 14 and 15 are shown. This is to make the examples easy to follow. If present in a real Run the Transfer List must also specify transfers to segments 1-13. Otherwise the transfer will occur to segments 1 and 2 on the first CD since segments with no specified transfer will be ignored during the Run.***

NOTE: ***Following examples refers to the use of CDs with 14 segments available.***

Example 1: 2 CDs Run with standard curve repeated for each CD

Figures included in this section show reagent and transfer lists from a Run with the purpose to use the same Standard series on a different CDs in a multiple CD Run. This requires that the Standard series samples and reagents are given different names in the reagent list (different **Reagent combination** names) and are put in different wells in the micro plate even though it has the same content. By giving the different **Reagent combinations** the same **Experiment name** they will be analyzed as one entity in Gyrolab Evaluator.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

	A	B	C	D	E	F	G
1	**MP Type (M)**	MP96 PCR	M=Mandatory	O=Optional			**Reagent list info**
2	**Name (M)**	**Type (M)**	**Concentration (M)/(N/A)**	**Unit (M)/(N/A)**	**Dilution Factor (O)**	**MP Name (M)**	**Well (M)**
3	Capture_CD_1	RB				Reagent_MP	A1
4	Capture_CD_2	RB				Reagent_MP	A2
5	Detection_CD_1	RB				Reagent_MP	B1
6	Detection_CD_2	RB				Reagent_MP	B2
7	Curve_CD_1_Blank	BL	0	ng/ml		Reagent_MP	C1
8	Curve_CD_1_Standard_1	STD	1	ng/ml		Reagent_MP	C2
9	Curve_CD_1_Standard_2	STD	10	ng/ml		Reagent_MP	C3
10	Curve_CD_1_Standard_3	STD	100	ng/ml		Reagent_MP	C4
11	Curve_CD_2_Blank	BL	0	ng/ml		Reagent_MP	D1
12	Curve_CD_2_Standard_1	STD	1	ng/ml		Reagent_MP	D2
13	Curve_CD_2_Standard_2	STD	10	ng/ml		Reagent_MP	D3
14	Curve_CD_2_Standard_3	STD	100	ng/ml		Reagent_MP	D4

Figure 13: Reagent list with the same Standard series repeated on a different CD in the same Run

Use Exact Mapping (M)	No	**Transfer list info**	**CD Type (O)**	Bioaffy	M=Mandatory
Segment (M)	**Structure (M)**	**Inlet (M)**	**Op_Capture reagent addition**	**Op_Analyte addition**	**Op_Detection reagent addition**
14	Common left	Common inlet	Capture_CD_1		Detection_CD_1
14	1	Structure inlet		Curve_CD1_Blank	
14	2	Structure inlet		Curve_CD1_Standard_1	
14	3	Structure inlet		Curve_CD1_Standard_2	
14	4	Structure inlet		Curve_CD1_Standard_3	
14	5	Structure inlet		Curve_CD1_Blank	
14	6	Structure inlet		Curve_CD1_Standard_1	
14	7	Structure inlet		Curve_CD1_Standard_2	
14	8	Structure inlet		Curve_CD1_Standard_3	
15	Common left	Common inlet	Capture_CD_2		Detection_CD_2
15	1	Structure inlet		Curve_CD2_Blank	
15	2	Structure inlet		Curve_CD2_Standard_1	
15	3	Structure inlet		Curve_CD2_Standard_2	
15	4	Structure inlet		Curve_CD2_Standard_3	
15	5	Structure inlet		Curve_CD2_Blank	
15	6	Structure inlet		Curve_CD2_Standard_1	
15	7	Structure inlet		Curve_CD2_Standard_2	
15	8	Structure inlet		Curve_CD2_Standard_3	
3	Common left	Common inlet	Capture_CD_2		Detection_CD_2

Figure 14: Transfer list with the same standard curve repeated on a different CD in the same Run

A 2-CD Run using a reagent and transfer list from current examples will generate following in Gyrolab Evaluator:

If not using an Experiment name

- Capture_CD 1_Detection_CD 1 (processed on CD 1)
- Capture_CD 2_Detection_CD 2 (processed on CD 2)
- Two Standard series in duplicates. One for each **Reagent combination**.

If using an Experiment name

- One combined set of reagents (**Experiment name**)
- One common Standard series in quadruplicates.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Example 2: A two CD Run with a common Experiment name

- One Standard series (CD1)
- Two Calibration Control samples (CD2)
- Eight Unknown samples, four on each CD (Sample List not shown)

The figures included in this example demonstrates Reagent and Transfer lists for a 2 CD Run using one Standard series on CD1 and Calibration Control samples on CD2. Unknown samples are present on both CDs. Using this strategy all Unknown samples will be quantified against the Standard series on CD 1.

	A	B	C	D	E	F	G
1	**MP Type (M)**	MP96 PCR	M=Mandatory	O=Optional			**Reagent list info**
2	**Name (M)**	**Type (M)**	**Concentration (M)/(N/A)**	**Unit (M)/(N/A)**	**Dilution Factor (O)**	**MP Name (M)**	**Well (M)**
3	Capture_CD_1	RB				Reagent_MP	A1
4	Capture_CD_2	RB				Reagent_MP	A2
5	Detection_CD_1	RB				Reagent_MP	B1
6	Detection_CD_2	RB				Reagent_MP	B2
7	Curve_CD_1_Blank	BL	0	ng/ml		Reagent_MP	C1
8	Curve_CD_1_Standard_1	STD	1	ng/ml		Reagent_MP	C2
9	Curve_CD_1_Standard_2	STD	10	ng/ml		Reagent_MP	C3
10	Curve_CD_1_Standard_3	STD	100	ng/ml		Reagent_MP	C4
11	CC1	CC	25	ng/ml		Reagent_MP	D1
12	CC2	CC	50	ng/ml		Reagent_MP	D2

Use Exact Mapping (M)	No	**Transfer list info**	**CD Type (O)**	Bioaffy	M=Mandatory
Segment (M)	**Structure (M)**	**Inlet (M)**	**Op_Capture reagent addition**	**Op_Analyte addition**	**Op_Detection reagent addition**
14	Common left	Common inlet	Capture_CD_1		Detection_CD_1
14	1	Structure inlet		Curve_CD1_Blank	
14	2	Structure inlet		Curve_CD1_Standard_1	
14	3	Structure inlet		Curve_CD1_Standard_2	
14	4	Structure inlet		Curve_CD1_Standard_3	
14	5	Structure inlet		#1	
14	6	Structure inlet		#2	
14	7	Structure inlet		#3	
14	8	Structure inlet		#4	
15	Common left	Common inlet	Capture_CD_2		Detection_CD_2
15	1	Structure inlet		CC1	
15	2	Structure inlet		CC2	
15	3	Structure inlet		CC1	
15	4	Structure inlet		CC2	
15	5	Structure inlet		#5	
15	6	Structure inlet		#6	
15	7	Structure inlet		#7	
15	8	Structure inlet		#8	
3	Common left	Common inlet	Capture_CD_2		Detection_CD_2

A two CD Run using current lists will generate following in Gyrolab Evaluator

- One Standard series
- Two Calibration Controls
- Eight Unknown samples, quantified against Standard series on CD 1

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

Example 3: A two CD Run with a common Experiment name

- Two Standard series (CD1 and CD2)
- Eight Unknown samples, four on each CD (Sample List not shown)

The figures included in this example demonstrates Reagent and Transfer lists for a two CD Run using two Standard series on separate CDs. Unknown samples are present on both CDs.

In spite of the use of a common **Experiment name**, using this strategy Unknown sample #1 -4 will be quantified against the Standard series on CD 1 and Unknown sample #5 -8 will be quantified against the Standard series on CD 2.

	A	B	C	D	E	F	G
1	MP Type (M)	MP96 PCR	M=Mandatory	O=Optional			Reagent list info
2	Name (M)	Type (M)	Concentration (M)/(N/A)	Unit (M)/(N/A)	Dilution Factor (O)	MP Name (M)	Well (M)
3	Capture_CD_1	RB				Reagent_MP	A1
4	Capture_CD_2	RB				Reagent_MP	A2
5	Detection_CD_1	RB				Reagent_MP	B1
6	Detection_CD_2	RB				Reagent_MP	B2
7	Curve_CD_1_Blank	BL	0	ng/ml		Reagent_MP	C1
8	Curve_CD_1_Standard_1	STD	1	ng/ml		Reagent_MP	C2
9	Curve_CD_1_Standard_2	STD	10	ng/ml		Reagent_MP	C3
10	Curve_CD_1_Standard_3	STD	100	ng/ml		Reagent_MP	C4
11	Curve_CD_2_Blank	BL	0	ng/ml		Reagent_MP	D1
12	Curve_CD_2_Standard_1	STD	1	ng/ml		Reagent_MP	D2
13	Curve_CD_2_Standard_2	STD	10	ng/ml		Reagent_MP	D3
14	Curve_CD_2_Standard_3	STD	100	ng/ml		Reagent_MP	D4

Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
14	Common left	Common inlet	Capture_CD_1		Detection_CD_1
14	1	Structure inlet		Curve_CD_1_Blank	
14	2	Structure inlet		Curve_CD_1_Standard_1	
14	3	Structure inlet		Curve_CD_1_Standard_2	
14	4	Structure inlet		Curve_CD_1_Standard_3	
14	5	Structure inlet		#1	
14	6	Structure inlet		#2	
14	7	Structure inlet		#3	
14	8	Structure inlet		#4	
15	Common left	Common inlet	Capture_CD_2		Detection_CD_2
15	1	Structure inlet		Curve_CD_2_Blank	
15	2	Structure inlet		Curve_CD_2_Standard_1	
15	3	Structure inlet		Curve_CD_2_Standard_2	
15	4	Structure inlet		Curve_CD_2_Standard_3	
15	5	Structure inlet		#5	
15	6	Structure inlet		#6	
15	7	Structure inlet		#7	
15	8	Structure inlet		#8	

A two CD Run using current lists will generate following in Gyrolab Evaluator

- Two Standard series
- Unknown sample #1 -4 will be quantified against the Standard series on CD 1
- Unknown sample #5 -8 will be quantified against the Standard series on CD 2.

© Copyright 2015 Gyros, Gyrolab User Guide, P0004354/H, D0023573/A

P0004354/H, D0023573/A

Corporate headquarters

Gyros AB

Uppsala Science Park
SE-751 83 Uppsala, Sweden

Visiting address:
Dag Hammarskjölds väg 52A

Tel +46 (0) 18 56 63 00

Fax +46 (0) 18 56 63 50

Regional sales office

Gyros Inc.

30 Technology Drive, Ste 1F
Warren, NJ 07059, USA

Tel +1 908 755 0011

Fax +1 908 755 0001

www.gyros.com

GYROS